IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC. Plaintiff/Counterclaim-Defendants, v. ANGIODYNAMICS, INC., Defendant/Counterclaim-Plaintiff.	)	C.A. No. 21-349-CFC

DEFENDANT AND COUNTERCLAIM-PLAINTIFF ANGIODYNAMICS, INC.'S ANSWER AND COUNTERCLAIMS TO PLAINTIFFS AND COUNTERCLAIM-DEFENDANTS C.R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S COMPLAINT

David E. Moore (#3983)
Bindu A. Palapura (#5370)
Andrew L. Brown (#6766)
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
abrown@potteranderson.com

Attorneys for Defendant/Counterclaim Plaintiff AngioDynamics, Inc.

OF COUNSEL:

John T. Moehringer
Danielle V. Tully
Michael B. Powell
CADWALADER, WICKERSHAM & TAFT LLP
200 Liberty Street
New York, NY 10281
Tel: (212) 504-6000

Dated: May 17, 2023
10817961 / 17409.00003

AngioDynamics, Inc. ("AngioDynamics"), Defendant in the above-entitled and numbered civil action, files this Answer and Counterclaims in response to the Complaint filed by Plaintiffs C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). The paragraph numbering in the Answer herein corresponds to the paragraph numbering in Bard's Complaint.

ANGIODYNAMICS'S ANSWER

THE PARTIES

1. AngioDynamics admits that the Complaint purports to assert an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* AngioDynamics denies all remaining allegations in this paragraph of the Complaint.

2. AngioDynamics is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint, and therefore denies these allegations.

3. AngioDynamics is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint, and therefore denies these allegations.

4. AngioDynamics admits that it is a corporation organized under the laws of the State of Delaware and has its principal place of business at 14 Plaza

Drive, Latham, NY 12110. AngioDynamics further admits that it makes, sells, offers for sale, and/or uses medical products, including implantable port products in the United States, including within this District.

JURISDICTION AND VENUE

5. AngioDynamics admits that the Complaint purports to assert a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* AngioDynamics denies all remaining allegations in this paragraph of the Complaint.

6. AngioDynamics admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. AngioDynamics admits that this Court has personal jurisdiction over AngioDynamics.

8. AngioDynamics admits that venue is proper in this judicial district.

THE PATENTS-IN-SUIT

9. AngioDynamics admits that U.S. Patent No. 8,025,639 ("the '639 Patent") is entitled "Methods of power injecting a fluid through an access port" and bears an issue date of September 27, 2011, but denies that the U.S. Patent and Trademark Office ("USPTO") legally issued the '639 Patent. AngioDynamics

admits that what appears to be a copy of the ’639 Patent is attached to the Complaint as Exhibit 1. AngioDynamics is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this paragraph of the Complaint, and therefore denies these allegations.

10. AngioDynamics admits that U.S. Patent No. 9,603,992 (“the ’992 Patent”) is entitled “Access Port Identification Systems and Methods” and bears an issue date of March 28, 2017, but denies that the USPTO legally issued the ’992 Patent. AngioDynamics admits that what appears to be a copy of the ’992 Patent is attached to the Complaint as Exhibit 2. AngioDynamics is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this paragraph of the Complaint, and therefore denies these allegations.

11. AngioDynamics admits that U.S. Patent No. 9,603,993 (“the ’993 Patent”) is entitled “Access Port Identification Systems and Methods” and bears an issue date of March 28, 2017, but denies that the USPTO legally issued the ’993 Patent. AngioDynamics admits that what appears to be a copy of the ’993 Patent is attached to the Complaint as Exhibit 3. AngioDynamics is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this paragraph of the Complaint, and therefore denies these allegations.

12. AngioDynamics is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint, and therefore denies these allegations.

ANGIODYNAMICS'S PRODUCTS

13. AngioDynamics admits that it makes, uses, imports, offers to sell, and/or sells the Smart Port CT power-injectable port, Smart Port CT low-profile power injectable port, and Smart Port CT Mini power-injectable port). AngioDynamics admits that it uses, offers to sell, and/or sells the BioFlo Ports with Endexo technology and the Xcela Plus ports. AngioDynamics denies the remaining allegations in this paragraph.

14. AngioDynamics admits that literature describing the Smart Port access port is available at https://www.angiodynamics.com/product/smart-port-ct-injectable-port/. AngioDynamics admits that Exhibit 4 appears to be a copy of literature previously available at https://www.angiodynamics.com/wpcontent/uploads/2020/10/Smart_Port_Power-Injectable_Port_Promotional_Literature-738739.pdf. AngioDynamics admits that Exhibit 5 appears to be a copy of literature available at https://www.angiodynamics.com/wp-content/uploads/2020/10/Smart_Port_Power-Injectable_Port_Poster-999204.pdf. AngioDynamics admits that Exhibit 6 appears to be a copy of literature available at https://www.angiodynamics.com/

product/smart-port-ct-injectable-port/. AngioDynamics admits that Exhibit 7 appears to be a copy of literature previously available at https://www.angiodynamics.com/ wpcontent/uploads/2020/10/Smart_Port_Tech_Note-991551.pdf. AngioDynamics admits that Exhibit 8 appears to be a copy of literature previously available at https://www.angiodynamics.com/wpcontent/uploads/2020/10/LifeGuard_Promotional_Literature-614411.pdf. AngioDynamics admits that Exhibit 9 appears to be a copy of literature previously available at https://www.angiodynamics.com/ wpcontent/uploads/2020/10/SmartPort_Patient_Education_Packet_14656995-01A-399816.pdf. AngioDynamics is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint, and therefore denies these allegations.

15. AngioDynamics admits that literature describing the BioFlo Ports with Endexo technology is available at https://www.angiodynamics.com/ product/bioflo-ports-with-endexo-technology/.

16. AngioDynamics admits that literature describing the Xcela Plus ports is available at https://www.angiodynamics.com/product/xcela-plus-ports/.

17. To the extent Paragraph 17 includes conclusions of law by using claim language whose meaning has not yet been construed by the Court, such

conclusions of law do not require a response and AngioDynamics on that basis denies them.

18. AngioDynamics admits that it makes, uses, imports, offers to sell, and/or sells infusion sets or components for use with its venous access ports, including the LifeGuard safety infusion set and the LifePort infusion sets.

ANGIODYNAMICS'S ANSWER TO BARD'S FIRST CAUSE OF ACTION

(Alleged Patent Infringement of the '639 Patent)

19. AngioDynamics incorporates by reference its responses to paragraphs 1–18 of the Complaint as though fully set forth herein.

20. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the '639 Patent, either literally or under the doctrine of equivalents and therefore denies all allegations in this paragraph of the Complaint.

21. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the '639 Patent. AngioDynamics specifically denies that it has performed any method patented by Bard.

22. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the '639 Patent. To the extent paragraph 22 includes conclusions of law by using claim language whose meaning has not yet been construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

23. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’639 Patent. To the extent paragraph 23 includes conclusions of law by using claim language whose meaning has not yet been construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

24. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’639 Patent. To the extent paragraph 24 includes conclusions of law by using claim language whose meaning has not yet been construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

25. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’639 Patent. To the extent paragraph 25 includes conclusions of law by using claim language whose meaning has not yet been construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

26. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’639 Patent. To the extent paragraph 26 includes conclusions of law by using claim language whose meaning has not yet been construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

27. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’639 Patent, either directly or indirectly.

28. AngioDynamics is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint, and therefore denies these allegations.

29. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’639 Patent, either directly or indirectly.

30. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 27–29, AngioDynamics denies the allegations of paragraph 30 of the Complaint.

31. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 27–30, AngioDynamics denies the allegations of paragraph 31 of the Complaint.

32. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 27–31, AngioDynamics denies the allegations of paragraph 32 of the Complaint.

33. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 27–32, AngioDynamics denies the allegations of paragraph 33 of the Complaint.

34. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 27–33, AngioDynamics denies the allegations of paragraph 34 of the Complaint.

35. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 27–34, AngioDynamics denies the allegations of paragraph 35 of the Complaint.

36. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’639 Patent, either directly or indirectly.

37. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’639 Patent, either directly or indirectly. AngioDynamics specifically denies that it has contributed to the infringement of any valid and enforceable claim of the ’639 Patent.

38. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraph 37, AngioDynamics denies the allegations of paragraph 38 of the Complaint.

39. AngioDynamics is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint, and therefore denies these allegations.

40. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’639 Patent, either directly or indirectly.

AngioDynamics specifically denies that it has willfully infringed the ’639 Patent, and that Plaintiffs are entitled to enhanced damages.

41. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’639 Patent, either directly or indirectly. AngioDynamics specifically denies that it has willfully infringed the ’639 Patent.

42. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’639 Patent, either directly or indirectly. AngioDynamics specifically denies that Bard is entitled to a permanent injunction.

ANGIODYNAMICS’S ANSWER TO BARD’S SECOND CAUSE OF ACTION

(Alleged Patent Infringement of the ’992 Patent)

43. AngioDynamics incorporates by reference its responses to paragraphs 1–42 of the Complaint as though fully set forth herein.

44. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’992 Patent, either literally or under the doctrine of equivalents and therefore denies all allegations in this paragraph of the Complaint.

45. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’992 Patent. To the extent paragraph 45 includes conclusions of law by using claim language whose meaning has not yet been

construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

46. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’992 Patent. To the extent paragraph 46 includes conclusions of law by using claim language whose meaning has not yet been construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

47. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’992 Patent. To the extent paragraph 47 includes conclusions of law by using claim language whose meaning has not yet been construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

48. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’992 Patent, either directly or indirectly.

49. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’992 Patent, either directly or indirectly.

50. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraph 48-49, AngioDynamics denies the allegations of paragraph 50 of the Complaint.

51. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’992 Patent, either directly or indirectly.

52. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 48–51, AngioDynamics denies the allegations of paragraph 52 of the Complaint.

53. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 48–52, AngioDynamics denies the allegations of paragraph 53 of the Complaint.

54. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 48–53, AngioDynamics denies the allegations of paragraph 54 of the Complaint.

55. AngioDynamics is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint, and therefore denies these allegations.

56. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’992 Patent, either directly or indirectly. AngioDynamics specifically denies that it has willfully infringed the ’992 Patent and that Plaintiffs are entitled to enhanced damages.

57. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’992 Patent, either directly or indirectly. AngioDynamics specifically denies that Bard is entitled to a permanent injunction.

58. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’992 Patent, either directly or indirectly. AngioDynamics specifically denies that Bard is entitled to a permanent injunction.

ANGIODYNAMICS’S ANSWER TO BARD’S THIRD CAUSE OF ACTION

(Alleged Patent Infringement of the ’993 Patent)

59. AngioDynamics incorporates by reference its responses to paragraphs 1–58 of the Complaint as though fully set forth herein.

60. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’993 Patent, either literally or under the doctrine of equivalents and therefore denies all allegations in this paragraph of the Complaint.

61. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’993 Patent. To the extent paragraph 61 includes conclusions of law by using claim language whose meaning has not yet been construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

62. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’993 Patent. To the extent paragraph 62 includes

conclusions of law by using claim language whose meaning has not yet been construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

63. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’993 Patent. To the extent paragraph 63 includes conclusions of law by using claim language whose meaning has not yet been construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

64. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’993 Patent. To the extent paragraph 64 includes conclusions of law by using claim language whose meaning has not yet been construed by the Court, such conclusions of law do not require a response and AngioDynamics on that basis denies them.

65. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’993 Patent, either directly or indirectly.

66. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’993 Patent, either directly or indirectly.

67. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraph 65–66, AngioDynamics denies the allegations of paragraph 67 of the Complaint.

68. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraph 65–67, AngioDynamics denies the allegations of paragraph 68 of the Complaint.

69. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 65–68, AngioDynamics denies the allegations of paragraph 69 of the Complaint.

70. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 65–69, AngioDynamics denies the allegations of paragraph 70 of the Complaint.

71. Inasmuch as the allegations of this paragraph of the Complaint are linked to the allegations of indirect infringement set out in paragraphs 65–70, AngioDynamics denies the allegations of paragraph 71 of the Complaint.

72. AngioDynamics is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint, and therefore denies these allegations.

73. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the ’993 Patent, either directly or indirectly. AngioDynamics specifically denies that it has willfully infringed the ’993 Patent, and that Plaintiffs are entitled to enhanced damages.

74. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the '993 Patent, either directly or indirectly. AngioDynamics specifically denies that Bard is entitled to a permanent injunction.

75. AngioDynamics denies that it has infringed or is infringing any valid and enforceable claim of the '993 Patent, either directly or indirectly. AngioDynamics specifically denies that Bard is entitled to a permanent injunction.

ANGIODYNAMICS'S ANSWER TO BARD'S PRAYER FOR RELIEF

76. AngioDynamics denies that Bard is entitled to any of the relief requested against AngioDynamics in paragraphs A through G of Bard's Prayer For Relief in its Complaint.

ANGIODYNAMICS'S DEFENSES

77. AngioDynamics asserts the following defenses specified below. AngioDynamics reserves the right to assert additional defenses pursuant to Rule 8(c) of the Federal Rules of Civil Procedure, the patent laws of the United States, and any other defenses, at law or in equity, that may now exist or that become known through the course of discovery in this action and/or changes in applicable law or regulations.

FIRST DEFENSE

(Failure To State A Claim)

78. Bard's purported claims against AngioDynamics are barred because the Complaint fails to state any claim upon which relief can be granted.

SECOND DEFENSE

(Non-Infringement)

79. Bard's purported claims against AngioDynamics are barred because AngioDynamics does not infringe and has not infringed any valid and enforceable claim of any of the '639, '992, and '993 Patents, either directly or indirectly, including particularly that AngioDynamics has not induced or contributed to any infringement, and AngioDynamics has commercially used the subject matter of the '639, '992, and '993 Patents at least one year before the priority date of the '639, '992, and '993 Patents.

THIRD DEFENSE

(Invalidity)

80. Bard's purported claims against AngioDynamics are barred because each of the '639, '992, and '993 Patents is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code § 101 *et seq.*, including without limitation, 35 U.S.C. §§ 102, 103, and/or 112.

FOURTH DEFENSE

(Improper Inventorship)

81. Bard's purported claims against AngioDynamics are barred because, upon information and belief, each of the '639, '992, and '993 Patents is invalid under Title 35 of the United States Code § 102(f) for improper inventorship.

FIFTH DEFENSE

(Estoppel and/or Waiver)

82. Bard's purported claims against AngioDynamics regarding each of the '639, '992, and '993 Patents are barred, in whole or in part, by the doctrines of estoppel and/or waiver. For example, as discussed *infra* in the Eighth Counterclaim, Bard has taken certain positions in litigations and PTAB proceedings involving these or similar patents covering the same technology. Bard is estopped from taking any contrary positions.

SIXTH DEFENSE

(Inequitable Conduct)

83. Bard's purported claims against AngioDynamics are barred because, upon information and belief, each of the '639, '992, and '993 Patents is unenforceable as a result of inequitable conduct on the part of Plaintiffs and/or their representatives during prosecution of patent applications leading to the issuance of

the ’639, ’992, and ’993 Patents. As discussed *infra* at Counterclaims ¶¶ 146-264, individuals owing a duty of candor to the United States Patent and Trademark Office (the “PTO” or “USPTO”), including applicants for the patents-in-suit, the attorney(s) prosecuting the applications that resulted in those patents, and others associated with Bard or any other predecessors-in-title to the patents-in-suit, engaged in inequitable conduct through concealment and/or affirmative misstatements of material information made to the PTO during prosecution. As the overwhelming circumstantial evidence will establish, these individuals acted with the intent to deceive the PTO or at least with a state of mind so reckless as to the consequences that it was the equivalent of intent. This inequitable conduct renders the patents-in-suit, as well as any other patents owned by Bard related to the same subject matter, unenforceable.

SEVENTH DEFENSE

(Limitation on Damages)

84. To the extent Bard seeks damages, any claim for damages for patent infringement asserted against AngioDynamics is barred, in whole or in part, under 35 U.S.C. § 286 (six year limitation), 35 U.S.C. § 287 (failure to mark/provide notice), and/or 28 U.S.C. § 1498 (use or manufacture for United States Government).

EIGHTH DEFENSE

(No Enhanced Damages)

85. Notwithstanding the foregoing bases of invalidity, non-infringement, and unenforceability of the patents-in-suit, any damages sought by Bard are limited by 35 U.S.C. § 284, and Bard is in no event entitled to enhanced damages.

NINTH DEFENSE

(Not an Exceptional Case)

86. Notwithstanding the foregoing bases of invalidity, non-infringement, and unenforceability of the patents-in-suit, Bard cannot prove that this is an exceptional case justifying an award of attorney's fees against AngioDynamics pursuant to 35 U.S.C. § 285. AngioDynamics had and continues to have multiple strong and reasonable defenses to each of the allegations in the Amended Complaint. In actuality, it is AngioDynamics which is entitled to an award of fees and other damages for Bard's exceptional conduct in bringing and maintaining this action, as detailed below.

TENTH DEFENSE

(No Entitlement to Injunctive Relief)

87. Notwithstanding the foregoing bases of invalidity, non-infringement, and unenforceability of the patents-in-suit, Bard cannot establish the prerequisites for an injunction as, at a minimum, any alleged injury is not immediate or irreparable, Plaintiff has an adequate remedy at law for any claims it can prove, and/or an injunction would not serve the public interest.

ANGIODYNAMICS'S COUNTERCLAIMS

THE PARTIES

1. Counterclaim-plaintiff AngioDynamics is a Delaware corporation with its principal place of business located in Latham, New York.

2. On information and belief, counterclaim-defendant C.R. Bard, Inc. ("CRB") is a New Jersey corporation with its principal place of business located in Murray Hill, New Jersey.

3. On information and belief, counterclaim-defendant Bard Peripheral Vascular, Inc. ("BPV") is an Arizona corporation with a place of business located in Tempe, Arizona. Upon information and belief, Bard Peripheral Vascular, Inc. is a wholly-owned subsidiary and operating division of C.R. Bard, Inc. (BPV and CRB collectively, "Bard" or "Counterclaim-Defendants").

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*

5. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Bard and venue is proper in this judicial district by reason, *inter alia*, of Bard instituting the present action in this District, Bard's substantial sales made in this District, and Bard's acts of infringement performed in this District.

7. This Court further has personal jurisdiction over Bard and venue is proper in this judicial district by reason of, *inter alia*, Bard instituting the present action in this District and Bard instituting and maintaining other cases against AngioDynamics in this District, including C.A. No. 2:15-cv-00218 (JFB) and C.A. No. 1:20-cv-01544 (CFC).

8. Further, Bard has previously vigorously asserted that it prefers to litigate in Delaware and that venue is proper in this State for actions between Bard and AngioDynamics. For example, in *C.R. Bard, Inc. et al. v. AngioDynamics, Inc.*, C.A. No. 1:15-cv-00218 (JFB), Bard affirmatively chose to file suit in the District of Delaware. Facing a subsequent motion to transfer, Bard instead explicitly argued

that "Bard's Preferred Forum is Delaware," and that venue was proper in the State. (*See* Plaintiff Bard's Opposition to Defendant AngioDynamics's Motion to Transfer Venue, D.I. 16 at 7, *C.R. Bard, Inc. et al. v. AngioDynamics, Inc.*, C.A. No. 1:15-cv-00218 (JFB).) Bard succeeded in keeping the case in this District.

9. Additionally, Bard has in fact agreed that the present counterclaims can be brought in this case. When AngioDynamics first sought to file counterclaims against Bard by amending its Answer in *C.R. Bard, Inc. et al. v. AngioDynamics, Inc.*, C.A. No. 1:20-cv-01544 (CFC), Bard opposed the amendment, and asserted that "Angio Should File Its Counterclaims in the 21-349 Action." (*See* Plaintiffs' Answering Brief in Opposition to AngioDynamics, Inc.'s Motion For Leave to Amend Answer And Counterclaims Under Rule 15(a)(2), D.I. 230 at 12, *C.R. Bard, Inc. et al. v. AngioDynamics, Inc.*, C.A. No. 1:20-cv-01544 (CFC).) Bard specifically stated that "nothing stops Angio from counterclaiming there."

FACTUAL BACKGROUND

10. AngioDynamics is a leading provider of groundbreaking, patient-focused medical products, and manufactures numerous products incorporating patented, market-leading technologies. AngioDynamics has a legacy of innovation dating to the company's founding in 1988 as a start-up in the heart of

"Catheter Valley"—a reference to the cluster of innovative medical device companies founded in the Queensbury, New York region.

11. Included in AngioDynamics's product offerings are medical devices known as peripherally inserted central catheters ("PICCs"). Like access ports, these are all medical products that are intended to provide long-term intravenous access into a patient's vasculature system without the need for repeated injections through the skin. PICCs are partially implanted devices, meaning that a portion of the catheter will remain external to the patient and a portion will be implanted within the patient's vasculature system.

12. PICCs are used for delivering antibiotics, nutrition, and medications, as well as for withdrawing blood. While these devices are often crucial for providing treatment, their use can lead to certain medical complications, including infections, catheter occlusions or blockages, catheter fractures, and the build-up of thrombus—*i.e.*, blood clots—on the portion of the catheter residing in the patient's blood stream.

13. PICCs are inserted via veins in the upper arms and tunneled through the blood vessels until the catheter tip reaches the superior vena cava.

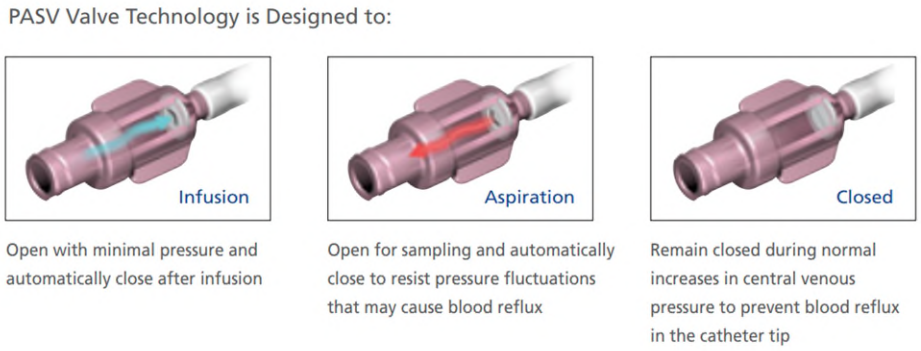
14. AngioDynamics offers a family of PICC products marketed under the tradename BioFlo. BioFlo catheters incorporate a one-of-kind additive

called Endexo, which drastically reduces the accumulation of thrombus—*i.e.*, blood clots—on the catheter surface.

15. Endexo is blended into the catheter polymer material during catheter manufacturing, including in extraluminal, intraluminal and cut catheter surfaces. The presence of Endexo at the cut surface is particularly important, as PICCs are trimmed before insertion to fit patients, and the cut end of the PICC, where thrombus buildup is most common, would still have Endexo on its surface. As a result, BioFlo catheters are associated with improved patient outcomes and help to avoid serious medical complications, such as deep vein thrombosis ("DVT"), stroke, and death.

16. In addition to offering PICCs incorporating BioFlo technology, AngioDynamics also offers products incorporating Pressure Activated Safety Valve ("PASV") technology. The PASV valve technology is a premium feature offered for certain AngioDynamics products, including the Xcela PICC and Vaxcel PICC.

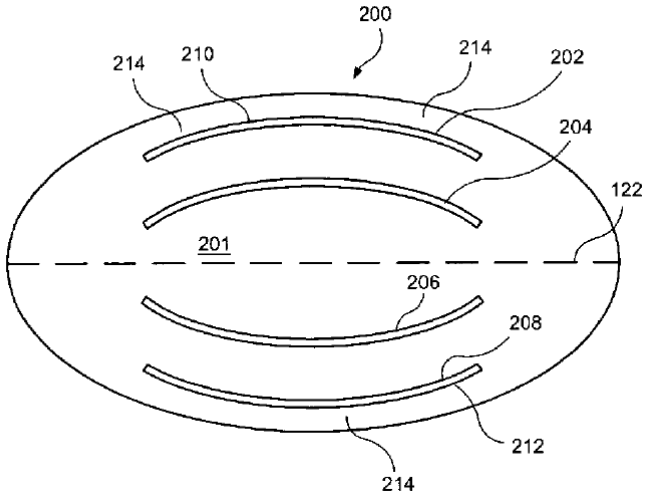
17. PASV valves are direction-specific valves that have been proven to improve patient outcomes, particularly with respect to catheter occlusion and patient infection.



18. PASV valves work by ensuring that slits on the valve membrane will open and close only under certain predetermined pressure conditions.

19. AngioDynamics has designed its PASV valves for high flow-rate applications, including power injection.

20. AngioDynamics's researchers have developed a patented design incorporating "Multi-Slit" technology. Multi-Slit technology relates to the use of multiple slits in the valve, which are designed to open under certain pressure thresholds and otherwise remain closed:



21. AngioDynamics's researchers have also developed a patented design incorporating "Grooved Valve" technology. Grooved Valves contain a groove on the surface of the valve's membrane, which improves fluid flow through the valve.

22. AngioDynamics's researchers have also developed a patented design incorporating "Double-Taper" technology. Double-Taper technology increases the ability of a catheter to safely withstand higher fluid flow rates while still retaining flexibility for smaller body lumens by providing a catheter with a thicker distal and proximal portion as compared to a middle portion. (*See* Ex. B at 1:10-21; Fig. 5).

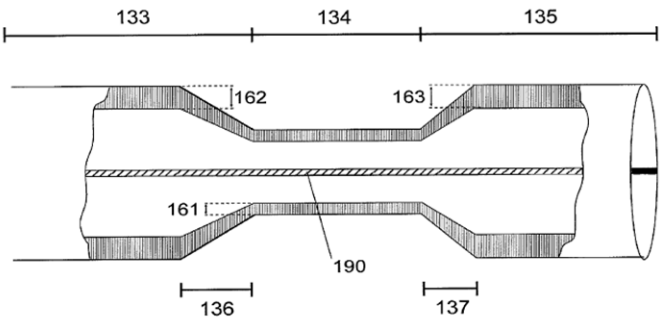


Figure 5

23. AngioDynamics owns several patents directed to Multi-Slit, Grooved Valve, and Double-Taper technologies.

24. AngioDynamics is the owner of U.S. Patent Nos. 8,377,011; 10,729,881; and 8,454,574; which relate to improvements in PASV valves, Multi-Slit PASV valves, Grooved Valve, and Double-Taper technologies (collectively, the "Asserted Patents").

25. On February 19, 2013, the USPTO duly and legally issued **US 8,377,011** (the "'011 Patent") to Karla Weaver and Paul D. DiCarlo, entitled "Pressure Activated Valve With High Flow Slit." A true and accurate copy of the '011 Patent is attached as Exhibit A.

26. On August 4, 2020, the USPTO duly and legally issued **US 10,729,881** (the "'881 Patent") to Raymond Lareau, Benjamin Bell, and Mark Girard, entitled "High Flow Catheters." A true and accurate copy of the '881 Patent is attached as Exhibit B.

27. On June 4, 2013, the USPTO duly and legally issued **US 8,454,574** (the "'574 Patent") to Karla Weaver and Paul D. DiCarlo, entitled "Pressure Activated Valve With Grooved Membrane." A true and accurate copy of the '574 Patent is attached as Exhibit C.

28. Upon information and belief, AngioDynamics has complied with the requirements of 35 U.S.C. § 287. Since issuance of each of the Asserted Patents, AngioDynamics has not made, offered for sale, sold, or imported a product that practices any of the Asserted Patents or that would otherwise require marking under 35 U.S.C. § 287.

BARD'S ACCUSED PRODUCTS

29. Bard makes, uses, imports, offers to sell, and/or sells PICC products, including the PowerPICC SOLO, PowerPICC SOLO 2, PowerPICC SOLO 2 HF, PowerPICC SOLO 2 FT, PowerPICC Provena SOLO, and PowerPICC FT (collectively, the "Accused Products").

30. Upon information and belief, each of the PowerPICC SOLO, PowerPICC SOLO 2, PowerPICC SOLO 2 HF, PowerPICC SOLO 2 FT, and PowerPICC Provena SOLO, as well as other similar Bard valved catheter products still to be discovered (the "Accused Valved Products") include a valve named the SOLO valve or SOLO 2 valve.

31. The SOLO and SOLO 2 valves are used in the Accused Valved Products to control the flow of fluids through the catheter, by staying closed without the need for a clamp and opening to allow the flow of fluids under certain pressure requirements.

32. Upon information and belief, the SOLO and SOLO 2 valves are materially identical and function in the same manner in each of the Accused Valved Products.

33. **Multi-Slit Valve Products.** The valves of the Accused Valved Products include three symmetrical slits disposed on an elliptical membrane, in which the three slits traverse the short axis of the membrane, which in turn bisects the long axis of the membrane.

34. **Grooved Valve Products.** The valves of the Accused Valved Products include a flexible membrane disposed in a valve housing, with the flexible membrane containing a proximal groove disposed on a first proximal surface adjacent to a slit.

35. **Double Taper.** Upon information and belief, each of the PowerPICC SOLO 2 FT, and PowerPICC FT, as well as other similar Bard catheter products still to be discovered (the "Accused Double Taper Products") include a catheter with a proximal section with a greater wall thickness and/or cross-sectional

diameter than an intermediate section and a distal section with a greater wall thickness and/or cross-sectional diameter than an intermediate section.

36. Literature describing Bard's **PowerPICC SOLO** products is available at https://res.onemed.com/SE/Produktblad/1030060.pdf. Provided herewith as Exhibit D is a true and correct copy of this literature.

37. A web page describing Bard's **PowerPICC SOLO** is available at https://accessgudid.nlm.nih.gov/devices/00801741128196. Provided herewith as Exhibit E is a true and correct copy of this web page.

38. A web page describing Bard's **PowerPICC SOLO 2** products is available at https://www.bd.com/en-us/products-and-solutions/products/product-families/powerpicc-solo2-catheter-ir. Provided herewith as Exhibit F is a true and correct copy of this web page.

39. A true and correct copy of literature published by Bard describing Bard's **PowerPICC SOLO 2** products is provided herewith as Exhibit G.

40. Literature describing Bard's **PowerPICC SOLO 2** products is available at https://www.henryschein.com/assets/Medical/1244958.pdf. Provided herewith as Exhibit H is a true and correct copy of this literature.

41. A true and correct copy of a Patient's Guide published by Bard for use of the **PowerPICC SOLO 2** products is attached herewith as Exhibit I.

42. A web page describing Bard's **PowerPICC SOLO 2 HF** products is available at https://www.bd.com/en-us/products-and-solutions/products/product-page.1395108Q#overview. Provided herewith as Exhibit J is a true and correct copy of this web page.

43. A web page describing Bard's **PowerPICC SOLO 2 FT** products is available at https://www.bd.com/en-us/products-and-solutions/products/product-page.3295335F#overview. Provided herewith as Exhibit K is a true and correct copy of this web page.

44. A web page describing Bard's **PowerPICC Provena SOLO** products is available at https://www.bd.com/en-us/products-and-solutions/products/product-families/powerpicc-provena-catheter. Provided herewith as Exhibit L is a true and correct copy of this web page.

45. A web page describing Bard's **PowerPICC Provena SOLO** products is available at https://www.bd.com/en-us/products-and-solutions/products/product-page.S1395108#overview. Provided herewith as Exhibit M is a true and correct copy of this web page.

46. Literature describing Bard's **PowerPICC FT** products is available at https://accessgudid.nlm.nih.gov/devices/00801741035715. Provided herewith as Exhibit N is a true and correct copy of this literature.

47. A true and correct copy of literature published by Bard describing the Accused Products is provided herewith as Exhibit O.

FIRST COUNTERCLAIM

(Infringement of U.S. Patent No. 8,377,011)

48. AngioDynamics re-alleges the allegations set forth in paragraphs 1 through 47 of its Counterclaims.

49. Counterclaim-Defendants have infringed, and continued to infringe, one or more claims of the '011 Patent by making, using, offering for sale, selling, and/or importing into the United States, valved catheter products, including the Accused Valved Products.

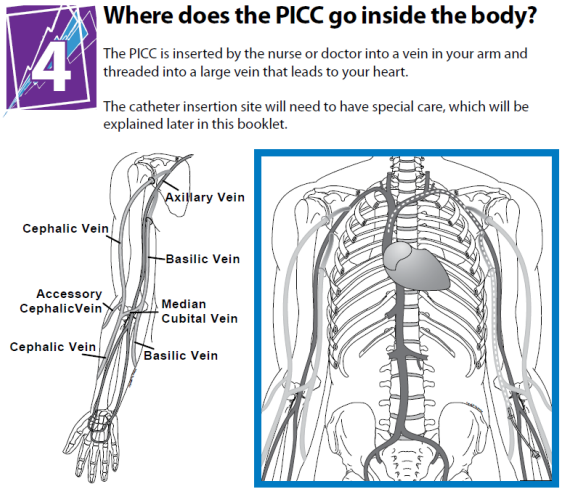
50. The products that infringe the '011 Patent include at least the Accused Valved Products made, marketed, distributed, sold, and/or offered for sale by Bard throughout the United States and in this District. These products include at least each and every limitation recited in at least exemplary Claim 1.

What is a PowerPICC SOLO* Catheter ?

PICC is a short name for "Peripherally Inserted Central Catheter", reflecting the fact that the catheter is inserted into a large vein in your arm (usually the basilic or cephalic vein). Unlike most catheters, the PowerPICC SOLO* catheter has a valve that allows liquids to flow in or out but it remains closed when it is not in use. The PowerPICC SOLO* catheter may also be used for contrast power injections at up to 5 ml/sec.

(Ex. I at 2).

51. Upon information and belief, each of the Accused Valved Products are systems for exchanging fluid between an external reservoir and a patient.



(Ex. I at 2).

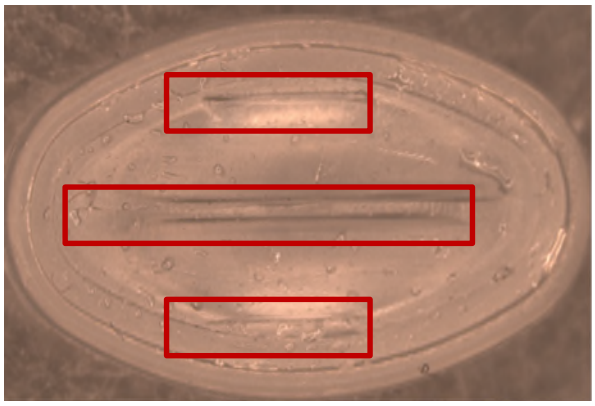
52. Upon information and belief, each of the Accused Valved Products include a catheter with at least one lumen, the catheter having a distal end insertable into a patient and a proximal end connected to at least one valve.

53. Upon information and belief, each of the Accused Valved Products includes a housing including a lumen extending therethrough, capable of fluid communication with a lumen of the catheter.

(Ex. D. at 1).

54. Upon information and belief, each of the Accused Valved Products contains an elliptical membrane extending across the lumen, the membrane including a plurality of slits disposed symmetrically within the membrane about a long axis of the membrane, and at least one slit disposed between at least two of the plurality of slits.

(Ex. F at 6).



55. Upon information and belief, for each of the Accused Valved Products, the slit disposed between at least two of the plurality of slits extends in substantially the same direction as the plurality of slits, and all the slits traverse a short axis that bisects the long axis.

56. Counterclaim-Defendants have committed and continue to commit all of the above acts of infringement without license or authorization.

57. Counterclaim-Defendants infringe literally and/or under the doctrine of equivalents.

58. Upon information and belief, Counterclaim-Defendants have known of the ’011 Patent and their infringement thereof since at least October 2018 and have investigated the ’011 Patent since that time. Upon information and belief, Counterclaim-Defendants also learned about the ’011 Patent and their infringement thereof through efforts to monitor and analyze AngioDynamics’s patent filings.

59. Upon information and belief, AngioDynamics has complied with the requirements of 35 U.S.C. § 287 with respect to the ’011 Patent to the extent any obligation to mark exists.

60. As a result of Counterclaim-Defendants’ infringement of the ’011 Patent, Plaintiff has suffered damages and will continue to suffer damages.

61. Counterclaim-Defendants’ infringement of the ’011 Patent has been and continues to be willful and deliberate.

62. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Counterclaim-Defendants’ wrongful conduct has caused and will continue to cause Counterclaim-Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others

from making, using, selling, offering to sell, and/or importing Counterclaim-Plaintiff's patented inventions. Upon information and belief, Counterclaim-Defendants will continue to infringe the '011 Patent unless permanently enjoined by this Court.

SECOND COUNTERCLAIM

(Infringement of U.S. Patent No. 10,729,881)

63. AngioDynamics re-alleges the allegations set forth in paragraphs 1 through 62 of its Counterclaims.

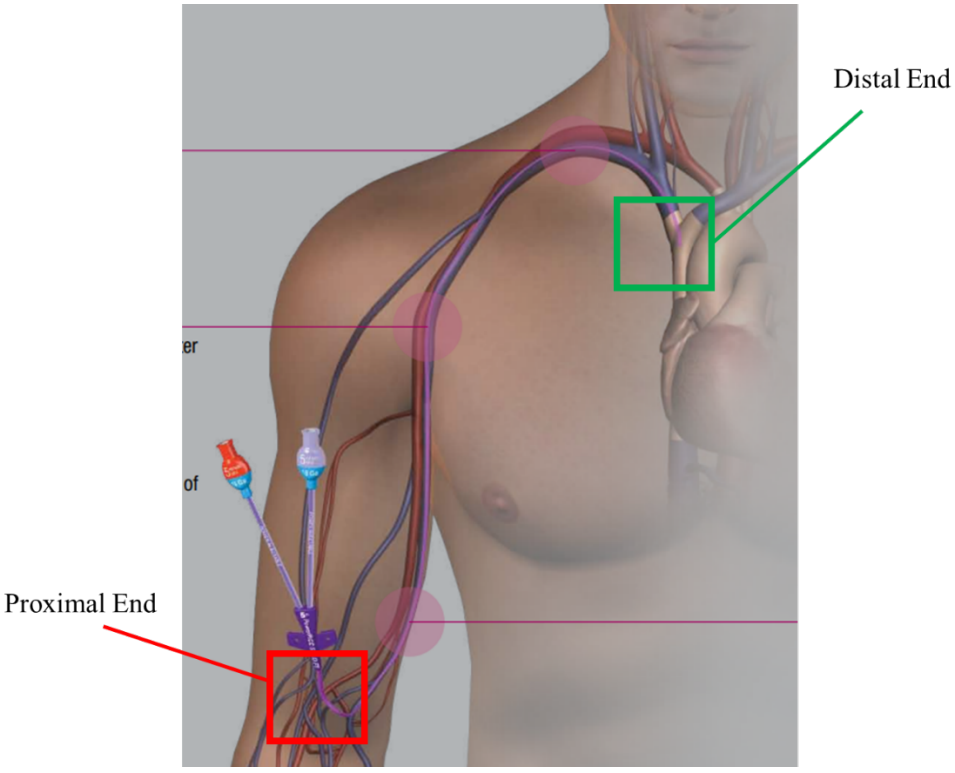
64. Counterclaim-Defendants have infringed, and continued to infringe, one or more claims of the '881 Patent by making, using, offering for sale, selling, and/or importing into the United States, catheter products, including the Accused Double Taper Products.

65. The products that infringe the '881 Patent include at least the Accused Double Taper Products made, marketed, distributed, sold, and/or offered for sale by Bard throughout the United States and in this District. These products include at least each and every limitation recited in at least exemplary Claim 1.

66. Upon information and belief, each of the Accused Double Taper Products are dual lumen catheters for access to a vascular system.

(Ex. H at 1).

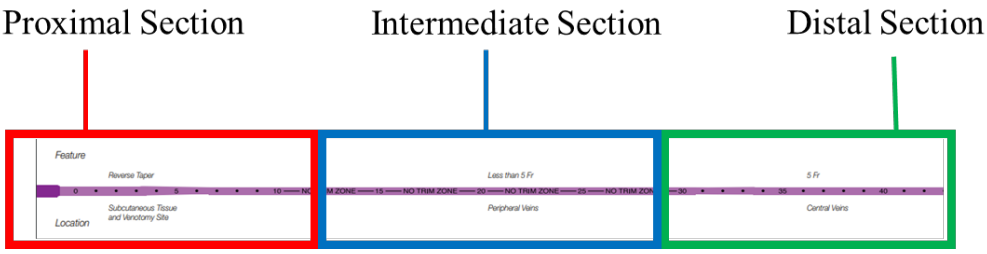
67. Upon information and belief, each of the Accused Double Taper Products include a catheter having a proximal end, a distal end, and two lumens therein extending from the proximal end to the distal end.



(Ex. H at 1).

(Ex. H at 2).

68. Upon information and belief, each of the Accused Double Taper Products has a proximal section that includes the proximal end, a distal section that includes the distal end, and an intermediate section extending between said proximal and distal sections, with each of the proximal, distal, and intermediate sections having a wall thickness.

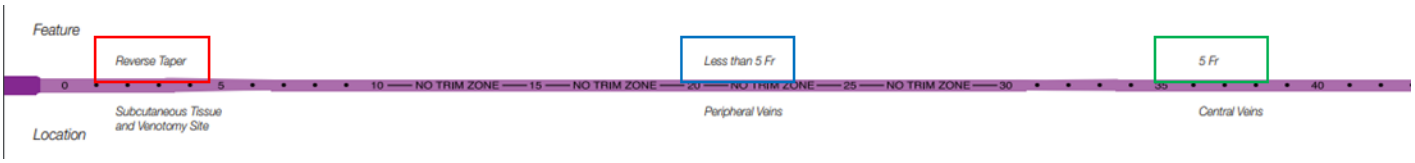


(Ex. H at 2).

69. Upon information and belief, for each of the Accused Double Taper Products, the wall thickness of the intermediate section is less than the wall thickness of the distal section, less than the wall thickness of the distal end, and less than the wall thickness of the proximal section.

> **Introducing the vascular access market's first PICC designed to better fit within the patient's veins. In addition to the reverse taper gently plugging the venotomy site, the PowerPICC SOLO*2 FT catheter provides a smaller diameter, more flexible middle section for the smaller peripheral deep veins of the upper arm and a larger diameter distal tip for the larger central veins.**

(Ex. H at 3).



(Ex. H at 2).

70. Counterclaim-Defendants have committed and continue to commit all of the above acts of infringement without license or authorization.

71. Counterclaim-Defendants infringe literally and/or under the doctrine of equivalents.

72. Upon information and belief, Counterclaim-Defendants have known of family members of the '881 Patent and their infringement thereof since at least October 2018, and have investigated the '881 Patent and the application culminating in the '881 Patent since that time. Upon information and belief, Counterclaim-Defendants also learned about the '881 Patent and their infringement thereof through efforts to monitor and analyze AngioDynamics's patent filings.

73. Upon information and belief, AngioDynamics has complied with the requirements of 35 U.S.C. § 287 with respect to the '881 Patent to the extent any obligation to mark exists.

74. As a result of Counterclaim-Defendants' infringement of the '881 Patent, Plaintiff has suffered damages and will continue to suffer damages.

75. Counterclaim-Defendants' infringement of the '881 Patent has been and continues to be willful and deliberate.

76. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Counterclaim-Defendants' wrongful conduct has caused and will continue to cause Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others from making, using, selling, offering to sell, and/or importing Plaintiff's patented inventions. Upon information and belief, Counterclaim-Defendants will continue to infringe the '881 Patent unless permanently enjoined by this Court.

THIRD COUNTERCLAIM

(Infringement of U.S. Patent No. 8,454,574)

77. AngioDynamics re-alleges the allegations set forth in paragraphs 1 through 76 of its Counterclaims.

78. Counterclaim-Defendants have infringed, and continued to infringe, one or more claims of the '574 Patent by making, using, offering for sale, selling, and/or importing into the United States, valved catheter products, including the Accused Valved Products that, when used according to Counterclaim-Defendants' instructions for use, practice at least Claim 1 of the '574 Patent.

79. Upon information and belief, Counterclaim-Defendants have performed a method of infusing fluid through a pressure activated valve of the Accused Valved Products to a target site, through their own use and testing of the Accused Valved Products.

- The **PowerPICC SOLO*2** catheter testing included 10 power injection cycles.

(Ex. G at 6).

80. Upon information and belief, each of the Accused Valved Products include a vascular access catheter having a pressure activated valve.

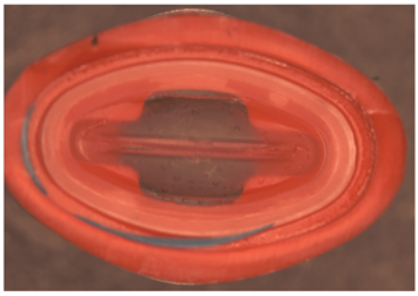
What is a PowerPICC SOLO* Catheter ?

PICC is a short name for "Peripherally Inserted Central Catheter", reflecting the fact that the catheter is inserted into a large vein in your arm (usually the basilic or cephalic vein). Unlike most catheters, the PowerPICC SOLO* catheter has a valve that allows liquids to flow in or out but it remains closed when it is not in use. The PowerPICC SOLO* catheter may also be used for contrast power injections at up to 5 ml/sec.

(Ex. I at 2).

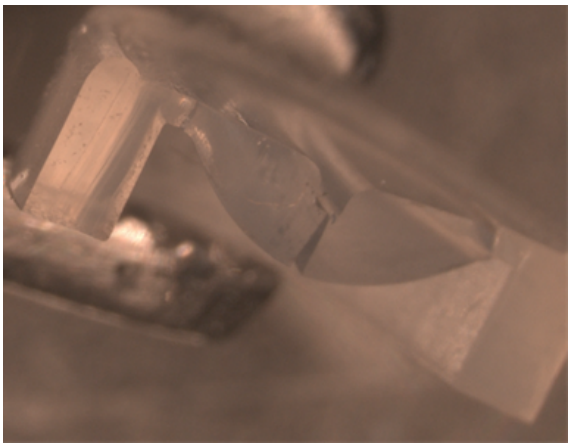
81. Upon information and belief, Bard has provided the Accused Valved Products to its customers, including hospitals and other medical institutions.

82. Upon information and belief, for each of the Accused Valved Products, the pressure activated valve contains a valve housing defining a lumen and a first flexible membrane disposed in the valve housing.

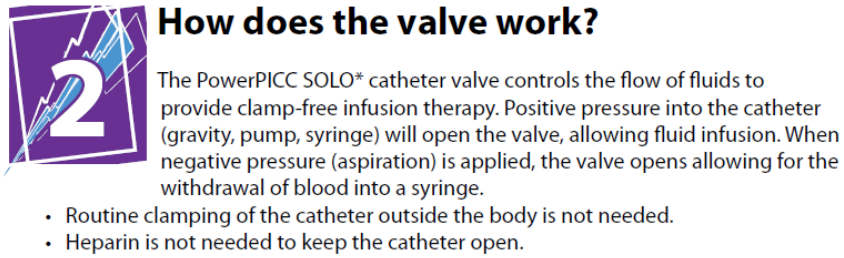


83. Upon information and belief, for each of the Accused Valved Products, the first flexible membrane has a substantially elliptical disk shape.

84. Upon information and belief, for each of the Accused Valved Products, the first flexible membrane has a first proximal surface, a first distal surface and the first flexible membrane therebetween.



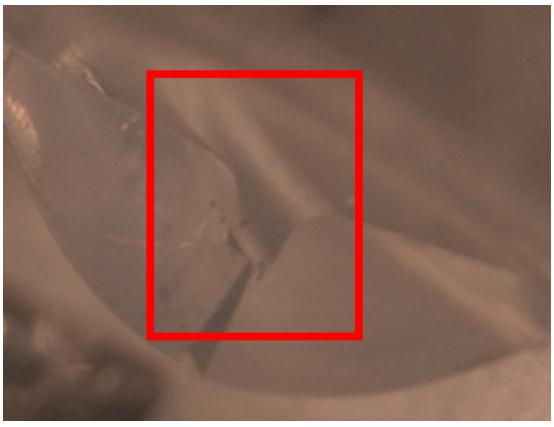
85. Upon information and belief, for each of the Accused Valved Products, the first flexible membrane includes a first slit extending through the first flexible membrane so that the first flexible membrane may be moved between an open and closed configuration based on a fluid pressure within the lumen.



(Ex. I at 2).

(Ex. F at 6).

86. Upon information and belief, for each of the Accused Valved Products, the first flexible membrane includes a proximal groove disposed on the first proximal surface and adjacent to the first slit to direct fluid flow towards the first slit.



87. Upon information and belief, Counterclaim-Defendants have infused fluid through the pressure activated valve of the Accused Valved Products to a target site.

- The **PowerPICC SOLO*2** catheter testing included 10 power injection cycles.

(Ex. G at 6).

88. In addition to directly infringing the ’574 Patent, Counterclaim-Defendants have indirectly infringed and continue to indirectly infringe the ’574 Patent by actively inducing others to directly infringe the ’574 Patent.

89. Upon information and belief, Counterclaim-Defendants have known of the ’574 Patent and their infringement thereof since at least October 2018, and have investigated the ’574 since that time. Upon information and belief, Counterclaim-Defendants also learned about the ’574 Patent and their infringement thereof through efforts to monitor and analyze AngioDynamics’s patent filings.

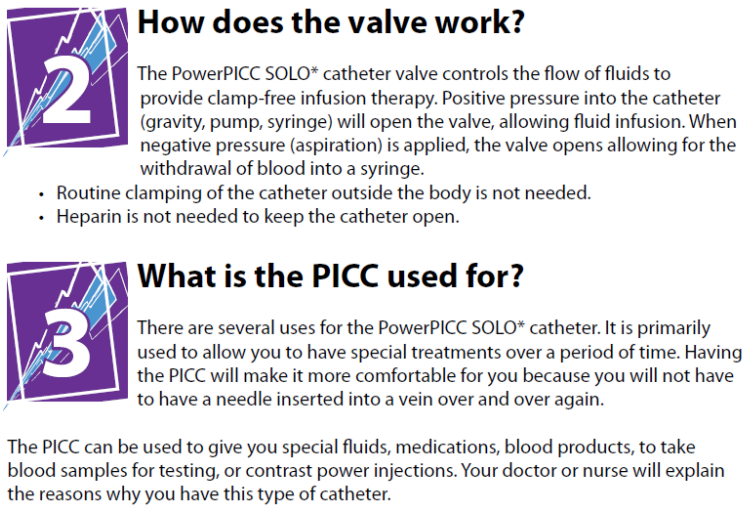
90. Upon information and belief, AngioDynamics has complied with the requirements of 35 U.S.C. § 287 with respect to the ’574 Patent to the extent any obligation to mark exists.

91. Despite Counterclaim-Defendants’ knowledge of the ’574 Patent, Counterclaim-Defendants have actively induced and continue to actively induce others to make, use, sell, and/or offer to sell in the United States, and/or

import into the United States, the Accused Valved Products in a manner that infringes one or more claims of the '574 Patent.

92. For example, upon information and belief, Counterclaim-Defendants' customers, including physicians, nurses, surgeons, medical technicians and other medical practitioners, are directly infringing the '574 Patent through their use of the Accused Valved Products, according to the instructions for use included with the Accused Valved Products.

93. For example, Counterclaim-Defendants advertise the Accused Valved Products as being used for the purpose of infusing fluid through a pressure activated valve to a target site.



How does the valve work?

The PowerPICC SOLO* catheter valve controls the flow of fluids to provide clamp-free infusion therapy. Positive pressure into the catheter (gravity, pump, syringe) will open the valve, allowing fluid infusion. When negative pressure (aspiration) is applied, the valve opens allowing for the withdrawal of blood into a syringe.

- Routine clamping of the catheter outside the body is not needed.
- Heparin is not needed to keep the catheter open.

What is the PICC used for?

There are several uses for the PowerPICC SOLO* catheter. It is primarily used to allow you to have special treatments over a period of time. Having the PICC will make it more comfortable for you because you will not have to have a needle inserted into a vein over and over again.

The PICC can be used to give you special fluids, medications, blood products, to take blood samples for testing, or contrast power injections. Your doctor or nurse will explain the reasons why you have this type of catheter.

(Ex. I at 2).

94. Upon information and belief, Counterclaim-Defendants include instructions for use with the Accused Valved Products to instruct medical professionals on how to use the Accused Valved Products.

95. Upon information and belief, the instructions issued by Counterclaim-Defendants instruct medical practitioners to infuse a fluid through the Accused Valved Products to a target site, such as during intravenous therapy, blood sampling, and power injection.

Indications

The **PowerPICC SOLO*2** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.

(Ex. G at 4).

96. Upon information and belief, Counterclaim-Defendants have knowingly induced infringement of the ’574 Patent, and have done so with the specific intent to induce such infringement, through the instructions for use Counterclaim-Defendants supply, as well as other training, marketing, advertising, support, or distribution of the Accused Valved Products. Upon information and belief, Counterclaim-Defendants are aware that the actions they induced would practice the claims of the ’574 Patent.

97. Counterclaim-Defendants actively publicize the ability of the Accused Valved Products to have fluid infused through the valve of the Accused Valved Products to target sites.

How does the valve work?

The PowerPICC SOLO* catheter valve controls the flow of fluids to provide clamp-free infusion therapy. Positive pressure into the catheter (gravity, pump, syringe) will open the valve, allowing fluid infusion. When negative pressure (aspiration) is applied, the valve opens allowing for the withdrawal of blood into a syringe.

- Routine clamping of the catheter outside the body is not needed.
- Heparin is not needed to keep the catheter open.

What is the PICC used for?

There are several uses for the PowerPICC SOLO* catheter. It is primarily used to allow you to have special treatments over a period of time. Having the PICC will make it more comfortable for you because you will not have to have a needle inserted into a vein over and over again.

The PICC can be used to give you special fluids, medications, blood products, to take blood samples for testing, or contrast power injections. Your doctor or nurse will explain the reasons why you have this type of catheter.

(Ex. I at 2).

98. In addition to directly infringing and inducing infringement of the ’574 Patent, Counterclaim-Defendants have infringed and continue to infringe the ’574 Patent indirectly, including by contributing to the infringement of the ’574 Patent.

99. Counterclaim-Defendants contribute to the infringement of the ’574 Patent by, for example, providing, importing, selling, and offering for sale within the United States and this District, the Accused Valved Products.

100. Each of the Accused Valved Products are vascular access catheters that can be used in infringing one or more claims of the ’574 Patent.

101. Upon information and belief, the Accused Valved Products were especially made or adapted for use in infringement of the ’574 Patent.

102. Upon information and belief, the Accused Valved Products are not staple articles or commodities of commerce suitable for substantial noninfringing use.

103. Counterclaim-Defendants have committed and continue to commit all of the above acts of infringement without license or authorization.

104. Counterclaim-Defendants infringe literally and/or under the doctrine of equivalents.

105. As a result of Counterclaim-Defendants' infringement of the '574 Patent, Plaintiff has suffered damages and will continue to suffer damages.

106. Counterclaim-Defendants' infringement of the '574 Patent has been and continues to be willful and deliberate.

107. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Counterclaim-Defendants' wrongful conduct has caused and will continue to cause Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others from making, using, selling, offering to sell, and/or importing Plaintiff's patented inventions. Upon information and belief, Counterclaim-Defendants will continue to infringe the '574 Patent unless permanently enjoined by this Court.

FOURTH COUNTERCLAIM

(Declaratory Judgment of Invalidity of U.S. Patent No. 8,025,639)

108. AngioDynamics re-alleges the allegations set forth in paragraphs 1 through 107 of its Counterclaims.

109. Based on Bard's filing of its Complaint and AngioDynamics's Defenses asserted against the Complaint, an actual controversy has arisen and now exists between the parties as to the validity of U.S. Patent No. 8,025,639 (the "'639 Patent").

110. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, AngioDynamics requests a declaration by the Court that the '639 Patent is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code § 101 *et seq.*, including particularly, 35 U.S.C. §§ 102, 103, and/or 112.

111. On November 10, 2020, the Federal Circuit explained that "AngioDynamics presented largely undisputed evidence that certain prior art ports, and the use of those ports, satisfied most of the remaining elements of the asserted claims, including power injectability . . . ." *C.R. Bard, Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1384 (Fed. Cir. Nov. 10, 2020). This same admitted and uncontroverted prior art renders Bard's Asserted Patents invalid under §§ 102 and 103.

112. Once the Court issues its claim construction rulings for the '639 Patent, and/or following an opportunity for further investigation and discovery, the evidence will likely establish that the claims of the '639 Patent are invalid as anticipated under 35 U.S.C. § 102 in light of prior art patents, printed publications and/or public use or on-sale activities. The '639 Patent claims are invalid as aforesaid, despite any potential applicability of any presumption pursuant to 35 USC § 282 because, *inter alia*, the Examiner overlooked the significance of many of the references and/or was erroneously convinced to allow the claims based on arguments and amendments which in fact had no patentable significance. Prior art to be relied on at trial will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, as part of contention discovery ordered by the Court.

113. Once the Court issues its claim construction rulings for the '639 Patent, and/or following an opportunity for further investigation and discovery, the evidence will likely establish that the claims of the '639 Patent are invalid as obvious under 35 U.S.C. § 103 in view of one or more of prior art patents, printed publications and/or public use or on-sale activities, when the teachings of those references are properly combined in accordance with the applicable legal principles as set out, *e.g.*, in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007). The '639 Patent claims are invalid as aforesaid, despite any potential applicability of any

presumption pursuant to 35 USC § 282 because, *inter alia*, the Examiner overlooked the significance of many of the references and/or was erroneously convinced to allow the claims based on arguments and amendments which in fact had no patentable significance. Prior art to be relied on at trial will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, as part of contention discovery ordered by the Court.

114. The ’639 Patent is invalid over prior art patents, printed publications and/or public use or on-sale activities even after the purported priority date pursuant to 35 U.S.C. § 102, whether alone or in combination with the knowledge of one skilled in the art and/or for obviousness under 35 U.S.C. § 103, because the ’639 Patent is not entitled to the priority date printed on the ’639 Patent. Prior art to be relied on at trial will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, in accordance with contention discovery ordered by the Court.

115. Following a reasonable opportunity for further investigation and discovery, evidence will likely support additional invalidity or unenforceability defenses, including, but not limited to, evidence that the alleged invention claimed in the ’639 Patent was placed on-sale or in public use in the United States by Bard or others more than one year prior to the filing date to which the ’639 Patent is properly entitled and/or taught or disclosed through other prior art information which

renders the '639 Patent claims invalid under 35 U.S.C. §§102 and/or 103. These references will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, as part of contention discovery ordered by the Court.

116. The claims of the '639 Patent are invalid under 35 U.S.C. § 112, ¶ 1 for failure to comply with the written description and/or enablement requirements and/or under 35 U.S.C. § 112, ¶ 2 for indefiniteness. Neither Provisional Application Nos. 60/737,466 nor 60/675,309, nor the Appendices thereto, nor the specification as originally filed with the U.S. App. No. 11/380,124, which issued as U.S. Patent No. 8,545,460 satisfies the requirements of 35 U.S.C. § 112, ¶¶ 1–2. The '639 Patent claims priority to both of these applications. Moreover, the phrase "material substantially free of plasticizer" as used in the '639 Patent is indefinite and renders the patent invalid under at least 35 U.S.C. § 112.

117. By reason of the foregoing, a conflict of asserted rights has arisen and a justiciable controversy currently exists between Bard and AngioDynamics with regard to the allegations of the validity of the '639 Patent. AngioDynamics hereby requests a declaratory judgment adjudicating its rights with respect to the '639 Patent—*i.e.*, that the claims of the '639 Patent are invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code § 101 *et seq.*, including particularly, 35 U.S.C. §§ 102, 103, and/or 112.

FIFTH COUNTERCLAIM

(Declaratory Relief Regarding Invalidity of U.S. Patent No. 9,603,992)

118. AngioDynamics re-alleges the allegations set forth in paragraphs 1 through 117 of its Counterclaims.

119. Based on Bard's filing of its Complaint and AngioDynamics's Defenses asserted against the Complaint, an actual controversy has arisen and now exists between the parties as to the validity of U.S. Patent No. 9,603,992 (the "'992 Patent").

120. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, AngioDynamics requests a declaration by the Court that the '992 Patent is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code § 101 *et seq.*, including particularly, 35 U.S.C. §§ 102, 103, and/or 112.

121. On November 10, 2020, the Federal Circuit explained that "AngioDynamics presented largely undisputed evidence that certain prior art ports, and the use of those ports, satisfied most of the remaining elements of the asserted claims, including power injectability . . . ." *C.R. Bard, Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1384 (Fed. Cir. Nov. 10, 2020). This same admitted and uncontroverted prior art renders Bard's Asserted Patents invalid.

122. Once the Court issues its claim construction rulings for the '992 Patent, and/or following an opportunity for further investigation and discovery, the evidence will likely establish that the claims of the '992 Patent are invalid as anticipated under 35 U.S.C. § 102 in light of prior art patents, printed publications and/or public use or on-sale activities. The '992 Patent claims are invalid as aforesaid, despite any potential applicability of any presumption pursuant to 35 USC § 282 because, *inter alia*, the Examiner overlooked the significance of many of the references and/or was erroneously convinced to allow the claims based on arguments and amendments which in fact had no patentable significance. Prior art to be relied on at trial will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, as part of contention discovery ordered by the Court.

123. Once the Court issues its claim construction rulings for the '992 Patent, and/or following an opportunity for further investigation and discovery, the evidence will likely establish that the claims of the '992 Patent are invalid as obvious under 35 U.S.C. § 103 in view of one or more of prior art patents, printed publications and/or public use or on-sale activities, when the teachings of those references are properly combined in accordance with the applicable legal principles as set out, *e.g.*, in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007). The '992 Patent claims are invalid as aforesaid, despite any potential applicability of any

presumption pursuant to 35 USC § 282 because, *inter alia*, the Examiner overlooked the significance of many of the references and/or was erroneously convinced to allow the claims based on arguments and amendments which in fact had no patentable significance. Prior art to be relied on at trial will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, as part of contention discovery ordered by the Court.

124. The ’992 Patent is invalid over prior art patents, printed publications and/or public use or on-sale activities even after the purported priority date pursuant to 35 U.S.C. § 102, whether alone or in combination with the knowledge of one skilled in the art and/or for obviousness under 35 U.S.C. § 103, because the ’992 Patent is not entitled to the priority date printed on the ’992 Patent. Prior art to be relied on at trial will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, in accordance with contention discovery ordered by the Court.

125. Following a reasonable opportunity for further investigation and discovery, evidence will likely support additional invalidity or unenforceability defenses, including, but not limited to, evidence that the alleged invention claimed in the ’992 Patent was placed on-sale or in public use in the United States by Bard or others more than one year prior to the filing date to which the ’992 Patent is properly entitled and/or taught or disclosed through other prior art information which

renders the '992 Patent claims invalid under 35 U.S.C. §§ 102 and/or 103. These references will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, as part of contention discovery ordered by the Court.

126. Upon information and belief, and as further investigation or discovery will show, the claims of the '992 Patent are invalid as indefinite under 35 U.S.C. § 112, ¶¶ 1–2. For example, none of the applications to which the '992 Patent claims priority include, *inter alia*, any disclosure of any description of a characteristic or structure of a power-injectable port, nor what constitutes a power-injectable port, nor how a generic radiopaque alphanumeric message can be used to convey that a port is power injectable.

127. By reason of the foregoing, a conflict of asserted rights has arisen and a justiciable controversy currently exists between Bard and AngioDynamics with regard to the allegations of the validity of the '992 Patent. AngioDynamics hereby requests a declaratory judgment adjudicating its rights with respect to the '992 Patent—*i.e.*, that the claims of the '992 Patent are invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code § 101 *et seq.*, including particularly, 35 U.S.C. §§ 102, 103, and/or 112.

SIXTH COUNTERCLAIM

(Declaratory Relief Regarding Invalidity of U.S. Patent No. 9,603,993)

128. AngioDynamics re-alleges the allegations set forth in paragraphs 1 through 127 of its Counterclaims.

129. Based on Bard's filing of its Complaint and AngioDynamics's Defenses asserted against the Complaint, an actual controversy has arisen and now exists between the parties as to the validity of U.S. Patent No. 9,603,993 (the "'993 Patent").

130. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, AngioDynamics requests a declaration by the Court that the '993 Patent is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code § 101 *et seq.*, including particularly, 35 U.S.C. §§ 102, 103, and/or 112.

131. On November 10, 2020, the Federal Circuit explained that "AngioDynamics presented largely undisputed evidence that certain prior art ports, and the use of those ports, satisfied most of the remaining elements of the asserted claims, including power injectability . . . ." *C.R. Bard, Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1384 (Fed. Cir. Nov. 10, 2020). This same admitted and uncontroverted prior art renders Bard's Asserted Patents invalid.

132. Once the Court issues its claim construction rulings for the '993 Patent, and/or following an opportunity for further investigation and discovery, the evidence will likely establish that the claims of the '993 Patent are invalid as anticipated under 35 U.S.C. § 102 in light of prior art patents, printed publications and/or public use or on-sale activities. The '993 Patent claims are invalid as aforesaid, despite any potential applicability of any presumption pursuant to 35 USC § 282 because, *inter alia*, the Examiner overlooked the significance of many of the references and/or was erroneously convinced to allow the claims based on arguments and amendments which in fact had no patentable significance. Prior art to be relied on at trial will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, as part of contention discovery ordered by the Court.

133. Once the Court issues its claim construction rulings for the '993 Patent, and/or following an opportunity for further investigation and discovery, the evidence will likely establish that the claims of the '993 Patent are invalid as obvious under 35 U.S.C. § 103 in view of one or more of prior art patents, printed publications and/or public use or on-sale activities, when the teachings of those references are properly combined in accordance with the applicable legal principles as set out, *e.g.*, in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007). The '993 Patent claims are invalid as aforesaid, despite any potential applicability of any

presumption pursuant to 35 USC § 282 because, *inter alia*, the Examiner overlooked the significance of many of the references and/or was erroneously convinced to allow the claims based on arguments and amendments which in fact had no patentable significance. Prior art to be relied on at trial will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, as part of contention discovery ordered by the Court.

134. The ’993 Patent is invalid over prior art patents, printed publications and/or public use or on-sale activities even after the purported priority date pursuant to 35 U.S.C. § 102, whether alone or in combination with the knowledge of one skilled in the art and/or for obviousness under 35 U.S.C. § 103, because the ’993 Patent is not entitled to the priority date printed on the ’993 Patent. Prior art to be relied on at trial will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, in accordance with contention discovery ordered by the Court.

135. Following a reasonable opportunity for further investigation and discovery, evidence will likely support additional invalidity or unenforceability defenses, including, but not limited to, evidence that the alleged invention claimed in the ’993 Patent was placed on-sale or in public use in the United States by Bard or others more than one year prior to the filing date to which the ’993 Patent is properly entitled and/or taught or disclosed through other prior art information which

renders the ’993 Patent claims invalid under 35 U.S.C. §§ 102 and/or 103. These references will be identified to Bard no later than thirty (30) days prior to trial pursuant to 35 U.S.C. § 282, if not sooner, as part of contention discovery ordered by the Court.

136. Upon information and belief, and as further investigation or discovery will show, the claims of the ’993 Patent are invalid as indefinite under 35 U.S.C. § 112, ¶¶ 1–2. For example, none of the applications to which the ’993 Patent claims priority include, *inter alia*, any disclosure of any description of a characteristic or structure of a power-injectable port, nor what constitutes a power-injectable port, nor how a generic radiopaque alphanumeric message can be used to convey that a port is power injectable.

137. By reason of the foregoing, a conflict of asserted rights has arisen and a justiciable controversy currently exists between Bard and AngioDynamics with regard to the allegations of the validity of the ’993 Patent. AngioDynamics hereby requests a declaratory judgment adjudicating its rights with respect to the ’993 Patent—*i.e.*, that the claims of the ’993 Patent are invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code § 101 *et seq.*, including particularly, 35 U.S.C. §§ 102, 103, and/or 112.

SEVENTH COUNTERCLAIM

(Declaratory Relief Regarding Improper Inventorship)

138. AngioDynamics re-alleges the allegations set forth in paragraphs 1 through 137 of its Counterclaims.

139. Based on Bard filing its Complaint and AngioDynamics's Defenses asserted against the Complaint, an actual controversy has arisen and now exists between the parties as to the validity of each of the '639, '992, and '993 Patents.

140. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, AngioDynamics requests a declaration by the Court that each of the '639, '992, and '993 Patents is invalid for improper inventorship under Title 35 of the United States Code § 102(f).

141. For example, the '639 Patent claims to be a continuation of U.S. App. No. 11/380,124, which issued as U.S. Patent No. 8,545,460. Nevertheless, the inventors named on the face of the '460 Patent—Jim C. Beasley and Kelly B. Powers—are almost entirely different than the inventors named on the '639 Patent—Kelly B. Powers, Guy T. Rome, John G. Evans, Dwight Hibdon, and David M. Cise.

142. Upon information and belief, Jim C. Beasley, who was listed as an inventor on the face of the '460 Patent, conceived and/or reduced to practice a

septum for use in a power-injectable port, as well as one or more structural features on a port for identifying the port as power-injectable.

143. Nevertheless, Bard filed a request to correct inventorship during prosecution of the '639 Patent, stating that the inventions of Jim Beasley were no longer being claimed in the application.

144. Similarly, each of the '992 and '993 Patents claim priority to U.S. Provisional App. No. 60/658,518 (the "'518 Provisional"), which named four inventors: Kevin W. Sheetz, Eddie K. Burnside, Matthew M. Lowe, and Jay D. Gerondale. The '992 and '993 Patents, however, name only sole inventor Kelly B. Powers, who was never named as an inventor on the '518 Provisional application.

145. Upon information and belief, this change in inventorship did not result from error without deceptive intent. It is believed that the foregoing contentions will likely have evidentiary support after a reasonable opportunity for further investigation and discovery.

EIGHTH COUNTERCLAIM

(Inequitable Conduct)

146. AngioDynamics re-alleges the allegations set forth in paragraphs 1 through 145 of its Counterclaims.

147. To properly serve the public interest, the USPTO and its examiners must receive truthful, accurate, and complete information to properly perform their duties.

148. This disclosure obligation is so important that federal law imposes a duty of good faith and candor upon each individual associated with the filing and prosecution of a patent. Further underscoring the importance of this disclosure obligation, a breach of this duty may constitute inequitable conduct, rendering a patent unenforceable.

149. Companies in the medical devices industry also owe duties of candor, disclosure, and good faith to the FDA when seeking 510(k) approval to market certain regulated medical devices. For example, when seeking 510(k) approval to market the PowerPort, Bard made certain sworn statements about the power injection capabilities of prior art access ports, including Bard's own prior art Adult Titanium Port.

150. Litigants in the federal courts also owe duties of candor, disclosure, and good faith to the federal judiciary. For example, Bard was obligated under the Federal Rules to ensure that it properly represented the state of the prior art during: (1) *C.R. Bard, Inc. et al. v. AngioDynamics, Inc.*, C.A. No. 1:15-cv-00218 (JFB), a case Bard filed in 2015 in the District of Delaware concerning substantially similar patents (the "First Delaware Action"); (2) *C.R. Bard, Inc. et al. v.*

AngioDynamics, Inc., No. 20-cv-01544 (CFC), originally filed in the District of Utah in 2012 and subsequently transferred to the District of Delaware in 2020, concerning substantially similar patents (the "Second Delaware Action").

151. Bard also was required under the Federal Rules to properly represent the state of the prior art in other litigations it commenced relating to the same or materially identical patents, including *C.R. Bard, Inc. et al. v. Medical Components*, C.A. No. 2:12-cv-0032, *C.R. Bard, Inc. et al. v. Smiths Medical ASD, Inc.*, C.A. No. 1:20-cv-1543, and *C.R. Bard, Inc. et al. v. Medical Components*, C.A. No. 2:17-cv-0754.

152. Bard is not permitted to make statements to various governmental entities, including the federal judiciary, that are mutually inconsistent. However, Bard did and is doing just that.

Kelly Powers, Todd Wight, Erik Ence, and Charles Krauss Withheld Material Information, Misrepresented the Prior Art, and Intended to Deceive the USPTO.

153. On information and belief, in breach of its duty of good faith and candor, by itself and through prosecuting counsel and the inventors of the Bard Asserted Patents, Bard misrepresented and withheld material information from the USPTO, including, but not limited to, the concealment of (i) decisions relevant to

the validity of the claims, (ii) knowledge that other prior art access ports were structured for power injection procedures, and (iii) knowledge of industry labeling practices, including the use of radiographic markers to identify implanted medical devices.

154. On information and belief, at least Bard prosecuting attorney Todd Wight ("Wight"), in-house counsel Erik Ence ("Ence") and Charles Krauss ("Krauss"), and named inventors of the '639, '992, and '993 Patents ("Bard's Asserted Patents") Kelly Powers ("Powers"), Guy T. Rome ("Rome"), John G. Evans ("Evans"), Dwight Hibdon ("Hibdon"), and David M. Cise ("Cise") (collectively, the "IC Individuals") each owed a duty of disclosure, good faith, and candor to the USPTO under 37 C.F.R. 1.56. On information and belief, the IC Individuals each violated this duty.

155. Mr. Powers is a named inventor of the patents Bard has asserted in this action and accordingly owed a duty of candor to the USPTO. In that capacity, he submitted sworn statements to the USPTO and participated in examiner interviews. Mr. Powers was also the technical lead for Bard's PowerPort project. In that capacity, he submitted sworn statements to the FDA, as well as documentation about the capabilities of Bard's commercial offerings. Mr. Powers has also been intimately involved in Bard's litigation campaign against AngioDynamics. In that

capacity, he has served as Bard's 30(b)(6) witness, technical consultant, and lead trial witness, as described *infra*.

156. On information and belief, as outside prosecution counsel, Mr. Wight directed Bard's patent procurement strategy, which required him to misrepresent the capabilities of prior art ports, including Bard's own prior art ports, and to omit Bard's knowledge of the prior art from the patent examiner. On information and belief, as in-house patent counsel for Bard, Messrs. Ence and Krauss participated in Bard's fraudulent patent procurement strategy along with other Bard employees, including at least Kelly Powers.

157. In particular, Messrs. Powers, Wight, Ence, and Krauss were, or should have been aware, of the teachings in the prior art and the obviousness of combining such teachings. However, on information and belief, these individuals failed to disclose this knowledge to the USPTO during the prosecution of Bard's Asserted Patents.

Bard Failed to Disclose the Herts Article—a Prior Art Reference Mr. Powers Conceded Was Material at Trial.

158. During prosecution, Bard and the IC Individuals were aware of the prior art article: "Power Injection of Contrast Media Using Central Venous

Catheters: Feasibility, Safety, and Efficacy," by Herts, et al. ("Herts"), appended as Exhibit P.

159. Herts discloses that BardPort devices—devices sold by Bard prior to any priority date of their Asserted Patents—were implanted in patients. (Ex. P at Appx31843.) Bard's own Adult Titanium Port is a BardPort device.

160. Herts discloses that implanted BardPort devices were used for power injection procedures. (*Id.*)

161. Herts discloses that implanted BardPort devices were safely power injected. (*Id.* at Appx31842, Appx31844, Table 1.)

162. Herts was not cited during the prosecution of Bard's Asserted Patents.

163. Herts was not explicitly brought to the attention of the Examiner during the prosecution of Bard's Asserted Patents.

164. During the First Delaware Action, Mr. Powers—who was also the named inventor on those substantially similar patents—testified that Bard knew about Herts and believed it to be sufficiently important to the subject of power injectability that Bard submitted Herts as part of its 510(k) submissions to the FDA. (*See* Ex. Q, Excerpts from Kelly Powers' Trial Testimony at 488:16–489:3, 633:20–634:20.)

165. Despite this clear knowledge of Herts and its subject matter, Herts was not provided to the USPTO during the prosecution of the Bard Asserted Patents. (*See* Complaint, Exs. 1, 2, and 3.)

166. Bard submitted Herts to the FDA but not to the USPTO.

167. Each of the IC Individuals had multiple opportunities to provide this material reference to the examiner.

Bard Failed to Disclose Its Knowledge that Prior Art Ports Were Power Injectable and Used for Power Injection Procedures.

168. Bard and the IC Individuals were also aware that prior art access ports were power injectable and being used for power injection procedures.

169. But Bard and the IC Individuals withheld this knowledge and information from the USPTO during prosecution of the Bard Asserted Patents, and further, made affirmative, knowingly false statements regarding the state of the art.

170. For example, in approximately June 2005, Bard and Mr. Powers began to determine whether and how to begin to market the access port which would become known as the PowerPort. A report was prepared named the Product Opportunity Appraisal (the "POA"), appended as Exhibit R, which analyzed the

current state of the art, including reviewing the extent to which practitioners were already using power injection procedures through conventional access ports.

171. The POA was reviewed and signed by multiple employees, including Mr. Powers, among others. (Ex. R at Appx33007.)

172. In the POA, "it [wa]s realized that other commercially available ports are capable of withstanding power injection." (*Id.* at Appx33011.)

173. Bard understood that even if it could be the first company to seek a formal indication from the FDA allowing Bard to market its ports as being capable of power injection, other companies were likely to quickly follow suit. (*See id.*)

174. The POA confirmed that Bard "anticipate[d] that our competitors are performing the testing needed to claim that their own ports are also compatible with power-injecting." (*Id.*)

175. Thus, Bard and the IC Individuals were aware that other access ports on the market were capable of withstanding power injection, and were concerned that competitors would soon seek indications from the FDA regarding such capability.

176. The knowledge that other access ports were capable of power injection is highlighted repeatedly in the POA.

177. For example, the POA discusses the "SIR 2004," a blind survey which reported that "many of the clinicians reported power injecting through non-indicated ports at their facility." (Ex. R at Appx33013.)

178. As another example, a footnote in the POA cites a communication with a physician named Dr. Scott Trerotola that took place on March 1, 2005. Per the footnote, Dr. Trerotola reported that "he had done his own study . . . showing that the HMP Vortex [Port] can withstand power injection pressures," and that Dr. Trerotola's facility used the Vortex Port for power injection. (*Id.* at Appx33045 n.17.)

179. As another example, the POA cited multiple reports and surveys prepared by Tom Beggs relating to use of power injection in the market.

180. These included a report dated December 17, 2004 and titled "Power Injectable Port: CT Technologists Perceptions Fall 2004," appended as Exhibit S. (*See, e.g.*, Ex. R at Appx33042 n.1 & n.4, Appx33043 n.11 & n.13.) This report described a survey of clinicians and practitioners, and the purpose of the study was described as getting the perspective of CT technologists "on the current use of ports for power injection." (Ex. S at Appx34412.) The report disclosed that "20% of [interventional radiologists] are already power injecting through ports." (*Id.*)

181. Based on the POA, the IC Individuals, including Mr. Powers in particular, were aware that power injection was being performed on commercially available prior art ports. (Ex. R at Appx33007.)

182. Bard did not submit Herts to the USPTO.

183. Bard and the IC Individuals were also aware from other sources that multiple, commercially available access ports were capable of withstanding power injection, including HMP's Vortex Port, Bard's own Adult Titanium Port, and Smiths' Port-A-Cath device.

184. For example, Bard and the IC Individuals were aware that the Vortex Port could withstand power injection, and was in fact being used for power injection procedures.

185. Bard and the IC Individuals were aware that the Vortex Port could withstand power injection, and was in fact being used for power injection procedures, in part through the communications it had with Dr. Trerotola, discussed *supra* at ¶ 178.

186. Bard and the IC Individuals were aware that its own previously-marketed Adult Titanium Port could also withstand power injection.

187. For example, Bard submitted testing data to the FDA in 2005, appended as Exhibit U, while seeking approval to market the PowerPort (an alleged

embodiment of the Bard Asserted Patents), showing that its own commercially available prior art Adult Titanium Port was suitable for power injection.

188. At least Mr. Powers had knowledge that this testing was being submitted to the FDA.

189. This testing was conducted directly on these prior art Adult Titanium Ports as "equivalent samples," and not on the device that would later be known as the PowerPort. (Ex. U, Excerpts from Bard's Section 510(k) submission to the FDA, at Appx31660, Appx31676, Appx31693, Appx31698, Appx31712, Appx31722-31723, Appx31725-31726.)

190. This equivalence was confirmed by, *inter alia*, Mr. Powers, who testified in the First Delaware Action that the Adult Titanium Ports were "equivalent" to the PowerPorts, including in all internal dimensions, and were capable of power injection. (Ex. Q at 571:18–576:17.)

191. Bard and the IC Individuals were aware that the prior art Port-A-Cath could also withstand power injection.

192. For example, Bard mailed surveys to numerous practitioners regarding their power injection practices and procedures. (*See, e.g.*, Ex. S at Appx34412.)

193. At least Mr. Powers was aware of and approved of this survey activity.

194. In response to one of these surveys, a practitioner noted that her hospital, Wayne Memorial Hospital, used the prior art Port-A-Cath for power injection procedures. (*See* Ex. V at Appx34293-34294.)

195. The practitioner went so far as to send Bard the protocol her hospital used for Port-A-Cath ports. (*Id.* at Appx34295.) This protocol specifically referenced a "power injector." (*Id.*)

196. That prior art ports were already power injectable and being used for power injection cannot be contested. On November 10, 2020, the Federal Circuit also recognized that prior art ports were capable of withstanding power injection and that "certain medical providers were using existing ports for power injection." *C.R. Bard, Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1375 (Fed. Cir. Nov. 10, 2020). The Federal Circuit specifically found that "Bard's commercially marketed vascular port product"—*i.e.*, Bard's 2005 Adult Titanium Port—"was already structurally suitable for power injection." *Id.*

197. The Federal Circuit based this conclusion on evidence produced from Bard's own files during the district court litigation. However, this same evidence was not provided to the USPTO.

198. Bard has no credible claim that these documents were or should have been confidential: they were used without restriction during trial in the First Delaware Action and in the ensuing Federal Circuit appeal.

199. Further, Bard's *knowledge* about the capabilities of and prior uses for commercially available, prior art access ports cannot be shielded from the USPTO because such information may have been retained in Bard's files as confidential. Once knowledge exists in the prior art, it cannot be removed from the IC Individuals' duty of disclosure via Bard's attempts to impose contractual confidentiality.

Bard Failed to Disclose Its Knowledge of Prior Art Labeling Practices, Including Use of Radiographic Markers.

200. Bard and the IC Individuals likewise withheld knowledge from the USPTO regarding labeling practices that were widespread in the prior art.

201. For example, Bard conducted surveys of the industry to identify the types of labeling that already existed for implanted medical devices. (*See, e.g.*, Ex. R at Appx33017, Appx33051-33053, Appx33057.) Through these surveys, Bard learned that those in the industry were routinely using radiographic markers to identify implanted medical devices.

202. At least Mr. Powers was aware of and approved of Bard's survey activity.

203. On information and belief, this relevant survey evidence was not submitted to the USPTO during the prosecution of the Bard Asserted Patents.

204. Bard and the IC Individuals were also aware during the prosecution of the Bard Asserted Patents that Bard's own commercially available Adult Titanium Port had features that were radiographically visible, which could be used to identify the Adult Titanium Port.

205. Specifically, Bard and the IC Individuals knew the commercially available Adult Titanium Port had a radiographically identifiable shape and suture hole configuration, as shown below:

206. Upon information and belief, Bard and the IC Individuals were also aware that the etching in the Adult Titanium Port was radiographically visible or could be made so via a trivial modification.

207. Bard and the IC Individuals were also aware during the prosecution of the Bard Asserted Patents that the commercially available Port-A-Cath had features that were radiographically visible which could be used to identify the Port-A-Cath.

208. Specifically, Bard and the IC Individuals knew that Port-A-Cath had a radiographically visible square shape and quadrilateral suture hole configuration, as shown below:

209. Bard cannot contest that radiographic labeling of prior art medical devices was known. On November 10, 2020, the Federal Circuit also recognized "Bard's admission that the use of radiographically identifiable markings on implantable medical devices was known in the prior art." *C.R. Bard, Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1384 (Fed. Cir. Nov. 10, 2020). Bard's own expert even recognized that radiographic marking technology has "gone on forever." (Ex. W, Excerpts from Dr. Timothy Clark's Trial Testimony, at 946:9-11.)

210. Bard has explicitly admitted that "it was known in the medical field prior to April 27, 2004 that medical devices intended to be implanted in humans could have radiographic markings that could identify information about the device after implantation." *See* Joint Proposed Pretrial Order, Ex. 1, "Statements of Uncontested Facts Requiring No Proof," D.I. 535-1 at 6, *C.R. Bard, Inc. et al. v. AngioDynamics, Inc.*, C.A. No. 1:15-cv-00218.

Bard's Pattern of Misstatements and Exaggerations Demonstrates Its Deceptive Intent.

211. Messrs. Powers, Ence, Krauss, and Wight each had the means, motive, and opportunity to mislead the USPTO about the state of the prior art. In particular, Mr. Powers would have had intimate knowledge about the capabilities of Bard's prior art ports, and about the industry generally, due to being Bard's PowerPort technology lead and a Bard liaison to the FDA.

212. Bard and the IC Individuals had affirmative duties to inform the USPTO about the Herts article, the power injection capability of prior art ports—including its own Adult Titanium Port—and the widespread labeling practices in the industry.

213. On information and belief, the IC Individuals did not share this material information with the USPTO.

214. On information and belief, the IC Individuals misrepresented the state of the prior art to the USPTO.

215. On information and belief, Bard made statements to the FDA, believing the statements would not become known by the USPTO.

216. While Bard's efforts to silo the information shared with the FDA may have succeeded long enough for the Bard Asserted Patents to issue, Bard's contradictions were exposed during the First Delaware Action when it had to disclose what it said to the FDA and USPTO. Even then, however, Bard continued to misrepresent the prior art and make statements contradicted by prior representations to the FDA.

During Prosecution of the Bard Asserted Patents, Bard Misrepresents and Omits its Knowledge of the Prior Art.

217. Bard's patent of deception runs deeper than the failure to disclose relevant prior art. The IC Individuals participated in examiner interviews with the USPTO in which they neglected to explain the capabilities of prior art ports, including Bard's own prior art ports, despite conducting demonstrations of the ports during the interviews. The also failed to explain Bard's knowledge of widespread labeling practices, including the use of radiographic markers.

218. For example, each of the ’992 and ’993 Patents claim priority through a chain of continuations to U.S. App No. 11/368,935, which issued as U.S. Patent No. 7,785,302 (the “’302 Patent”). Therefore the knowing misstatements and omissions made by Bard and the IC Individuals during prosecution of the ’302 Patent apply equally to the ’992 and ’993 Patents, rendering them unenforceable.

219. In a May 6, 2010 Interview with the Examiner during prosecution of the ’302 Patent attended by Messrs. Wight, Ence, Powers, and Krauss, the parties discussed amendments to the independent claims, including specifically “the attribute [of] being power injectable.” (*See* Ex. X, Excerpts from the ’302 Patent File History, at 2, May 6, 2010 Examiner Interview Summary Record.) The independent claims were subsequently amended to include, *inter alia*, limitations for identifying the ports as “power injectable” or “suitable for power injection.” (*See id.* at 4–7, June 2, 2010 Amendment.) The Examiner allowed the claims following this amendment. (*See id.* at 15, June 24, 2010 Notice of Allowance (“Claims 47, 52, 57, and 61 have been indicated allowable because the prior art of record fails to disclose either singly or in combination the claimed device of an implantable access port that has a radiopaque alphanumeric message to indicate that this port is *specifically power injectable*.” (emphasis added).).) All the while, however, the IC Individuals knew, but withheld, material information that the prior art ports already had the attribute of being power injectable.

220. During prosecution of the '302 Patent, the IC Individuals failed to disclose that ports structured for power injection, including Bard's own prior art Adult Titanium Port, had long existed in the art. For example, on May 6, 2010, the IC Individuals participated in an in-person interview with the Examiner and presented the PowerPort as a new type of port capable of withstanding power-injection to "further describ[e] the port and the attribute [of] being power injectable." (*See* Ex. X at 2.) During this interview, Bard and the IC Individuals failed to disclose to the Examiner that Bard had (i) identified the PowerPort to the FDA as "substantially equivalent" to its commercially available prior art Adult Titanium Port, (*see* Ex. U at Appx31660, Appx31676, Appx31693, Appx31712, Appx31722-31723); (ii) successfully conducted power-injection testing on the Adult Titanium Port in 2005, (*see id.* at Appx31698, Appx31725-31726); and (iii) submitted the results of this testing to the FDA in 2005 for purposes of approval to market the PowerPort, (*see generally id.*), as discussed *supra*:

Interview Summary	Application No. 11/368,954	Applicant(s) SHEETZ ET AL.	
	Examiner Aarti Bhatia Berdichevsky	Art Unit 3763	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Aarti Bhatia Berdichevsky*.

(2) *Nick Lucchesi*.

(3) *Todd Wight*.

(4) *Kelly Powers*
(5) Erik Ence
(6) Charles Krauss.

Date of Interview: *06 May 2010*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *access port shown*.

Claim(s) discussed: *42*.

Identification of prior art discussed: *Inamed Lap-Band Brochure*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Discussed potential amendments to independent claims to include the alpha-numeric radiopaque feature, as well as further describing the port and the attribute as being power injectable.*

(*See* Ex. Y at 2 (annotated).)

221. But for the withholding of this material information and the IC Individuals' affirmative misstatements regarding the state of the art, the claims of the '302 Patent would not have issued.

222. Similarly, during the prosecution of U.S. Patent No. 7,947,022 (another patent related to the '992 and '993 Patents to which the '993 claims direct priority), in an Interview with the Examiner on March 8, 2011 attended by Mr. Wight, the parties discussed overcoming a prior art rejection by "amending the claims to include limitations related to the engraved alphanumeric feature that

identifies the port as power injectable." (Ex. Y, Excerpts from the '022 Patent File History, at 2, March 8, 2011 Examiner Interview Summary Record.) The Applicant promptly amended the claims by, *inter alia*, including a reference to the port being "a power-injectable port." (*See id.* at 6–7, March 10, 2011 Amendment to Claims.) The claims were further amended to add that the identification feature included "one or more alphanumeric characters." (*See id.*) Following an additional telephonic interview between the Examiner and Mr. Wight, (*see id.* at 18), a Notice of Allowance was issued for the claims, subject to an Examiner's Amendment requiring that the "identification features" recited in the claims be "radiopaque." (*See id.* at 17–20, April 1, 2011 Notice of Allowance.) All the while, however, the inventors and the prosecuting attorney knew, but withheld, material information about the prior art.

223. Similarly, the '639 Patent claims priority to U.S. App. No. 11/380,124, which issued as U.S. Patent No. 8,545,460 (the "'460 Patent"). Therefore the knowing misstatements and omissions made by Bard and the IC Individuals during prosecution of the '460 Patent apply equally to the '639 Patent, rendering it unenforceable.

224. During prosecution of the '460 Patent, Bard continued to rely on power injectability to provide novelty for the claims, despite being aware that prior art ports were already capable of power injection. For example, in the final

amendment before allowance, Bard's only change was to identify that the applicable identifiable feature was a "radiographic marker." (Ex. Z at 2.) But for these misstatements, the '460 Patent would not have issued. As the '639 Patent claim priority to the application that issued as the '460 Patent, the misstatements and omissions made during prosecution of that patent apply equally to the '639 Patent.

225. Similarly, during prosecution of the '639 Patent itself, Bard continued to rely on the power injectability feature despite being aware that prior art ports had the same capability. For example, in the final amendment prior to allowance, Bard amended the claims to include "accommodating a pressure developed within the cavity of at least 35 psi." (Ex. AA at 2.) However, Bard was aware that prior art ports could already accommodate such pressures. (*See, e.g.*, Ex. U at Appx31660, Appx31676, Appx31693, Appx31698, Appx31712, Appx31722-31723, Appx31725-31726; Ex. P at Appx31842, Appx31844, Table 1; Ex. R at Appx33011.) Had Bard made the USPTO aware of this information, at least Claim 1 of the '639 Patent would not have issued.

226. But for the withholding of this material information, the claims of the Bard Asserted Patents would not have issued.

Contemporaneously, Bard Makes Materially Inconsistent Statements to the FDA in Order to Gain Marketing Approval for the PowerPort.

227. The sworn statements contemporaneously submitted to the FDA and USPTO cannot both be true. But at least Mr. Powers was integral to the creation and submission of both sets of statements.

228. Bard itself acknowledged that commercially available prior art access ports (such as the Vortex Port, Adult Titanium Port, and Port-A-Cath) were capable of withstanding power injection. (*See* Ex. R at Appx33011 ("[I]t is realized that other commercially available ports are capable of withstanding power injection.").)

229. In order to create a market opportunity to monopolize sales of power injectable ports, Bard attempted to obtain a patent on the identification of its ports. (*See id.* at Appx33012 ("[T]he opportunity is not in developing the product technology to withstand the pressures, but rather in developing the method of distinguishing capable ports from incapable ones . . . . If we can protect our identification means, this competitive advantage should be sustainable.").)

230. It was therefore critical for Bard's port business that patents issue, and therefore Bard and the IC Individuals would have been incentivized to withhold any documents or information that could prevent those patents from

issuing. Such documents and information included knowledge that commercially available prior art ports were capable of withstanding power injection, and that such ports already had methods of identifying them as having such a capability.

Bard Continues to Misrepresent its Knowledge of the Prior Art During USPTO Proceedings Concerning the '302 Patent.

231. Bard continued to make different representations to the USPTO regarding the state of the prior art as its interests changed. For example, on October 28, 2009, while prosecuting Application No. 11/368,954 (the "'954 Application"), which issued as the '302 Patent, an affidavit was filed by Kenneth Eliasen (the "Affidavit"), appended as Exhibit BB, who was identified as an expert for Bard.

232. The purpose of the Affidavit, as provided for in the Affidavit, was to provoke an interference with another patent application. (Ex. BB ¶10.)

233. The Affidavit was intended to help convince the USPTO that an interference should be instituted. It was successful in that respect.

234. In the Affidavit, Bard, through Mr. Eliasen, made statements inconsistent with statements it made during the subsequent Reexamination proceedings—namely, that the claims were patentable at least in part because of the location of the radiographic marker. These shifting positions highlight Bard's pattern of deceit before the USPTO.

235. Upon information and belief, Erik Ence was the in-house IP attorney responsible for overseeing a reexamination of the '302 Patent (the "'302 Reexam").

236. For example, in the Affidavit, Bard, through Mr. Eliasen, affirmatively represented that placement of a radiopaque marker on the surface of a housing base would have been "obvious to a person of ordinary skill in the art," and "would have only involved ordinary creativity on behalf of the designer." (Ex. BB ¶ 27; *see also id.* ¶ 38.)

237. Bard, through Mr. Eliasen, further represented that "[t]here are only a limited number of locations where radiopaque markings can be placed on the venous access port." (Ex. BB ¶ 27; *see also id.* ¶¶ 29, 37.) As a result, placing such a radiopaque marking on any of these locations would have been obvious to try. (*See id.* ¶¶ 29, 38.)

238. In particular, Bard, through Mr. Eliasen, represented that "the outside surface of the housing base location would have been obvious to try [to place a radiographic feature], as evidenced by the fact that nearly every port has a lot number and/or company logo printed, embossed, engraved, etc. on the bottom of the housing base." (Ex. BB ¶ 38.) As a result, "one of ordinary skill in the art…would have immediately thought to put the radiopaque markings on the housing base." (*Id.*)

239. Bard, through the deposition of its 30(b)(6) designee, Kenneth Eliasen, in the First Delaware Action, confirmed that the statements contained in the Affidavit fully apply to the 2005 timeframe, (Ex. CC, Excerpts from the August 15, 2017 Kenneth Eliasen 30(b)(6) Dep. Tr., at 99:6–100:6, 102:9-19, 106:2-16), were true and correct at the time Eliasen signed the Affidavit, and remain true and correct today, (*id.* at 88:2-10, 98:22–99:5, 102:9-16, 106:17-23).

240. Despite the sworn statements in the Eliasen Affidavit, Bard then took the opposite position in prosecution and in opposing reexamination of, *inter alia*, the '302 patent.

241. For example, despite Bard's acknowledgement in the Affidavit that placement of the radiopaque marker would have been obvious, Claim 1 of the '302 Patent explicitly claims a "housing base including radiopaque alphanumeric characters." (*See* Ex. DD, '302 Patent at Claim 1.)

242. During the '302 Reexam, in diametric opposition to the statements made in the Affidavit, Bard argued that the above claim 1 was valid because the placement of the radiopaque marker was *not* obvious. For example, Bard stated that "there is no rationale, teaching or suggestion provided by the examiner as to why a POSA would move the identification tag . . . to the housing base (claim 1), to a surface of the housing base (claim 2), or to the outwardly facing bottom surface of the housing base (claim 3)." (Ex. EE at 21.) Bard further argued that "the

examiner's statement that at the time of the invention, it would have been obvious to a POSA to position the radiopaque alphanumeric characters at any location on the access port…is not only unsubstantiated, it is incorrect." (Ex. EE at 21–22 (emphasis in original).)

243. Bard further argued that "[i]t would not have been obvious to position the radiopaque alphanumeric characters anywhere on the housing of the [prior art device] . . . ." (Ex. EE at 22.)

244. Further, during the reexamination of, *inter alia*, the '302 patent, Bard repeatedly maintained that a port's power-injectability—and that this, alone—was sufficient to overcome the cited prior art as, per Bard, none of the prior art disclosed or even suggested power-injectable ports. For instance, Bard argued that "[t]he prosecution history of the application maturing into the '302 patent (i.e., Application No. 11/368,954) renders it clear that the claims were allowed because the claims are directed to power injectable ports" and that because "none of the prior art cited by the examiner and the requester discloses, nor even suggests a power injectable port, claims 1-10 [of the '302 Patent] patentable over the cited prior art at least for this reason." (Ex. FF at 2, 9.) Further, during the June 18, 2015 Reexam hearing for, *inter alia*, the '302 patent, Bard argued that "the original Examiner understood and allowed the claims because they were directed to power [injectable]

ports." (Ex. GG at 12.) Bard argued that a point of novelty—the reason the patents were granted—was the power injectability of the claimed port.

245. Relying on these arguments, the Patent Trial and Appeal Board maintained the validity of at least Claim 3 of the '302 Patent.

246. Bard's position in the '302 Reexam is diametrically opposed to its position in the Affidavit. (*Compare* Ex. EE at 21–22, *with* Ex. BB ¶¶ 27, 29, 37, 38.)

247. Upon information and belief, in-house IP counsel Erik Ence was responsible for approving the diametrically opposed positions, despite knowing such positions were diametrically opposed, in the Affidavit and the '302 Reexam.

248. Bard argued diametrically opposed positions in the Affidavit and '302 Reexam in order to pursue its goal of maintaining and asserting patents that could help it maintain a competitive advantage in the port access market, regardless of the validity or enforceability of those patents. It changed its stance on the status of the prior art as its interests changed. When it needed to argue against a competitor's patent, Bard asserted in the Affidavit that the placement of a radiographic marker on a port was obvious. (Ex. BB ¶¶ 27, 28, 38.) When it needed to defend its own patent, Bard asserted in the '302 Reexam that the placement of a radiographic marker on a port was not obvious. (Ex. EE at 21–22.)

249. Bard also made statements in prosecution of the Bard Asserted Patents that are diametrically opposed to the statements in the Affidavit. During prosecution of each of the ’992 and ’993 Patents, Bard relied on the placement of radiopaque identification feature as a point of novelty. For example, in the final amendment before allowance in each prosecution, Bard amended the claims to include that the identifier was “positioned on the outwardly facing bottom surface[.]” (Ex. HH at 2-3; Ex. II at 2-3.) Had Bard provided the Examiner with the Affidavit, at least Claim 1 of the ’992 and Claim 1 of the ’993 Patents would not have issued.

250. In considering the totality of the circumstances, the specific intent by Bard to mislead and deceive the USPTO is the single most reasonable inference able to be drawn.

Bard Continues Its Pattern of Deception in Litigation.

251. Bard’s pattern of deception continued during multiple litigations it has initiated against AngioDynamics in multiple fora. As a litigation consultant and lead trial witness, Mr. Powers in particular took part in these deceptive practices. Upon information and belief, Bard’s in-house attorneys were also party to these practices, including, but not limited to, Mr. Ence.

252. Bard’s misrepresentations reflect information that is material to the invalidity of the Bard Asserted Patents, and its conduct in maintaining that position in the USPTO and throughout this action constitutes sufficient

circumstantial evidence of intent to deceive so as to establish unenforceability for inequitable conduct and/or unclean hands, as pleaded hereinafter. *See Regeneron Pharmaceuticals v. Merus N.V.*, Case No. 2016-1346 (Fed. Cir. 2017).

253. During the First Delaware Action, Bard continued to assert in litigation that the so-called "power-injectable port" was the key limitation and heart of the patents-in-suit, and that Bard invented a so-called power-injectable access port. (*See, e.g.*, Bard's Opposition to AngioDynamics's Motion to Dismiss, D.I. 18 at 1, *C.R. Bard, Inc. et al. v. AngioDynamics, Inc.*, C.A. No. 1:15-cv-00218 ("The patents-at-issue are directed to a power injectable access port—a man-made *machine* that is unambiguously patentable subject matter under 35 U.S.C. § 101. The power injectable access port is the key limitation of the patents-at-issue and the heart of the inventions."); Bard's Opening Claim Construction Brief, D.I. 83 at 1, C.A. No. 1:15-cv-00218 ("[C]onventional access ports are not suitable for performing power injection . . . . To solve this serious problem, the patents-in-suit teach . . . how to structure a port that is suitable for accommodating the fluid flow and pressure rates of a power injection procedure[.]"); Bard's Combined Opening and Answering Summary Judgment Brief regarding Eligibility, D.I. 286 at 4-5, C.A. No. 1:15-cv-00218 ("At the time of Bard's invention, conventional access ports were unsuitable for power injection . . . . [E]ven if an access port were, *in theory*, sufficiently robust for power injection, healthcare providers had no way of knowing that . . . . To solve

[this] problem, Bard's patents teach several ways to structure an access port so that it can withstand . . . power injection." (emphasis added).) Bard made these statements under Rule 11 despite making diametrically opposed statements to the FDA. In view of the assertions in Bard's complaint, Bard appears to be making similar arguments here.

254. Bard has also continued to misrepresent its knowledge of prior art label practices and the ease with which radiographic markers can be applied to ports. As Bard testified through its corporate 30(b)(6) witness, Kenneth Eliasen ("Eliasen"), a former Bard access port engineer, any attribute that was sufficiently unique could be used to identify a port as power injectable. Eliasen testified that such attributes could include, for example, the shape, design, or suture hole configurations of a port. (Ex. CC at 147:10–148:18, 153:18–156:21.)

255. Eliasen has previously made sworn statements, while submitting a declaration for Bard in support of a USPTO interference action concerning the '302 Patent, that few locations exist to place radiopaque markings on an access port, that moving the radiopaque markings would be obvious to try, and, in particular, that placing radiopaque markings on the bottom of the access port would have been obvious to try. (*See supra*, ¶¶ 231-39.)

256. At deposition as Bard's 30(b)(6) designee—*i.e.*, when speaking for Bard and affirmatively binding the company—Eliasen further explained that

putting radiopaque markings on the bottom of an access port would have been "the thing that is the most obvious to someone who is of ordinary skill" because "it would be the first place I would try," and because "anyone looking at this would likely try that first." (Ex. CC at 104:10–105:25.)

257. Eliasen, in his capacity as a 30(b)(6) witness for Bard, further testified that it would have been obvious to incorporate the radiopaque features taught by numerous prior art references, in particular the Jones and Carter prior art references, onto the housings of access ports. (*Id.* at 114:20–115:10.)

258. Eliasen, in his capacity as a 30(b)(6) witness for Bard, further testified that incorporating "radiopaque paint" as a radiographic marking would have been "very simple" because "[i]t's already a process that might have been incorporated into the overall manufacturing of the device. It doesn't require any necessar[y] modification to the housing or anything like that. It's just additive." (*Id.* at 121:8-22.)

259. Eliasen, in his capacity as a 30(b)(6) witness for Bard, further testified that it would have been obvious to add an alphanumeric character to a radiographic marker. (*Id.* at 131:5-9.)

260. Eliasen, in his capacity as a 30(b)(6) witness for Bard, testified that the statements he made in his previous 1.32 declaration in support of the

interference request applied to the 2005 timeframe. (*Id.* at 99:6–100:6, 102:9-19, 106:2-16.)

261. Eliasen, in his capacity as a 30(b)(6) witness for Bard, also affirmed that the statements in his declaration remained true and correct. (*Id.* at 88:2-10, 98:22–99:5, 102:9-16, 106:17-23.)

262. On March 13, 2023, in the First Delaware Action, Judge Bataillon admonished Bard that "[t]here were ports that were power injectable before [Bard's] patents" but, despite this, Bard repeatedly "made the claim that [it] w[as] the first to invent power injection" at the November 2022 jury trial in *C.R. Bard, Inc. et al. v. AngioDynamics, Inc.*, C.A. No. 1:15-cv-00218. (Ex. JJ at 45:15–47:16.) Judge Bataillon also chastised Bard's counsel, saying to him "[d]on't lie to me" when Bard's counsel conflated being the first to receive FDA approval with it inventing the first port, further noting that Bard "tried to patent the FDA approval." (*Id.*)

263. In considering the totality of the circumstances, the specific intent by Bard to mislead and deceive the USPTO is the single most reasonable inference able to be drawn.

264. Bard's inequitable conduct renders the '639, '992, and '993 Patents unenforceable.

ANGIODYNAMICS'S PRAYER FOR RELIEF

WHEREFORE, AngioDynamics respectfully requests that the Court:

(A) enter judgment in favor of AngioDynamics and against Bard;

(B) dismiss the Complaint against AngioDynamics with prejudice;

(C) declare that AngioDynamics has not infringed, under any theory of infringement, any valid and enforceable claim of each of the '639, '992, and '993 Patents;

(D) declare that each of the claims in each of the '639, '992, and '993 Patents is invalid and/or unenforceable;

(E) enter an order stating that AngioDynamics is not liable to Bard for any damages;

(F) rule that Bard has directly, indirectly and willfully infringed the '011; '881; and '574 Patents;

(G) permanently enjoin Bard, its affiliates, parent companies, and subsidiaries, and each of its officers, agents, servants, and employees, and those acting in privity or concert with it, from directly or indirectly infringing any of the claims of the '011; '881; and '574 Patents, and from causing or encouraging others to directly infringe the '011; '881; and '574 Patents;

(H) award damages under 35 U.S.C. § 284 in an amount sufficient to compensate AngioDynamics for its damages arising from Defendant's direct and

indirect infringement of the ’011; ’881; and ’574 Patents, including, but not limited to, lost profits and/or a reasonable royalty, together with prejudgment and post-judgment interest, and costs;

(I) award an accounting and/or supplemental damages for all damages occurring after any discovery cutoff and through the Court’s decision regarding the imposition of a permanent injunction;

(J) declare that this case is exceptional and award AngioDynamics its reasonable attorneys’ fees pursuant to 35 U.S.C. § 285; and

(K) grant AngioDynamics such other and further relief as the Court deems just and appropriate.

JURY DEMAND

AngioDynamics hereby demands trial by jury on all issues so triable.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ David E. Moore*
David E. Moore (#3983)
Bindu A. Palapura (#5370)
Andrew L. Brown (#6766)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
abrown@potteranderson.com

Attorneys for Defendant/Counterclaim Plaintiff AngioDynamics, Inc.

OF COUNSEL:

John T. Moehringer
Danielle V. Tully
Michael B. Powell
CADWALADER, WICKERSHAM & TAFT LLP
200 Liberty Street
New York, NY 10281
Tel: (212) 504-6000

Dated: May 17, 2023
10817961 / 17409.00003